كلية .....

نموذج تقييم بروتوكول مشروع بحثى (الكليات الطبية)

PROTOCOL REVIEW CHECKLIST (For Medical Sector)

IRB # _____

Title of Research Protocol

PI:

Purpose/Background/Justification	Briefly summarize the study purpose, background, and justification.			
	Adequate?			
SOCIAL VALUE	Yes	No [If no, explain in comments]	N/A	Comments
• Does the study address an important question of community/national interest?				
• Does the literature review justify the study?				
• Does the community need to be involved in the design, implementation, and dissemination of the results of the study?				

	Adequate?			
STUDY DESIGN	Yes	No [If no, explain in comments]	N/A	Comments
• Is the scientific design (e.g., qualitative design, placebo-control, phase III, etc.) of the study appropriate?				
• Are the objectives well described?				
• Are the techniques as to how the objectives will be measured well described?				
• Are the study groups clearly described?				
• Is the sample size and type of statistical analysis well described?				
• Are data analysis plans adequately described?				
• Are experimental interventional/procedures clearly distinguished from standard of care interventions?				
• Can the study as described in this protocol answer the research question it is designed to answer, and thus contribute to generalizable knowledge?				
SELECTION OF SUBJECTS AND RECRUITMENT	Yes	No [If no, explain]	N/A	Comments
• Considering the purpose of the research, is the selection of subjects fair? That is, are recruitment practices designed so that the research will not unfairly burden or unfairly benefit a particular population to the exclusion of others?				
• Are inclusion criteria described?				
• Are exclusion criteria described?				
• Does any compensation for participation (e.g., financial, prospects				

of free medical care) represent an undue inducement?				
• Does the setting of recruitment represent a coercive concern?				
• Are withdrawal criteria for individual subjects adequately described?				
VULNERABLE SUBJECTS	Yes	No [If no, explain in comments]	N/A	Comments
• Does the study involve vulnerable groups and if yes, are there additional protections?				
▪ Additional protections for minors				
▪ Additional protections for people lacking decisional capacity				
▪ Additional protections for prisoners				
▪ Additional protections for students or employees of institution				
▪ Additional protections for other vulnerable groups				

RISK /BENEFIT ASSESSMENT	Yes	No [If no, explain in comments]	N/A	Comments
• Are the following foreseeable risks present and clearly defined?				
▪ Physical risks?				
▪ Social risks?				
▪ Psychological risks?				
▪ Legal/political risks?				
▪ Economic risks?				
• Are risks minimized as much as possible (e.g., appropriate exclusion criteria, substitution of less risky interventions, etc)?				
• Are the procedures performed at proper facilities by appropriate providers?				

• Are there potential benefits to individuals, and if so, are they described?				
• Are the potential benefits to society well described?				
• FINAL ASSESSMENT: Are risks to subjects reasonable when compared to anticipated benefits?				

DATA AND SAFETY MONITORING	Yes	No [If no, explain in comments]	N/A	Comments
• Are statistical stopping rules (i.e., interim analysis) adequately described?				
• Is there a data safety monitoring board?				
• Are plans to monitor and report adverse events appropriate?				

	Adequate?			
INFORMED CONSENT	Yes	No [If no, explain in comments]	N/A	Comments
• Is the description of the informed consent process well described?				
• Are the consent forms /assent forms included? (see consent form checklist for assessment)				
• Will informed consent and/or assent be obtained from all potential subjects or legally authorized representatives?				

SUBJECT PRIVACY	Yes	No [If no, explain in comments]	N/A	Comments
Are provisions to protect subject privacy adequate (e.g., interviews will take place in private spaces)?				

	Adequate?			
CONFIDENTIALITY OF DATA COLLECTED	Yes	No [If no, explain in comments]	N/ A	Comments
• Are provisions to maintain confidentiality of collected data described and are adequate?				
• Will there be any future storage of tissue samples? If yes, please answer the following:				
○ Will there be genetic analysis of the stored tissue samples?				
○ Are the provisions to maintain the confidentiality of the stored tissue specimens reasonable (consider whether the samples will be identifiable or whether a code will be used to link to identifiers)?				
○ Will subjects have the option to withdraw their samples at any time?				
○ Are there plans to re-contact subjects with the findings of any health-related results?				
○ Are there appropriate limits on future use of the samples to particular institution, researchers, or type of disease?				
OTHER CONSIDERATIONS				
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INFORMED CONSENT DOCUMENTS				Refer to checklist
REVIEWER RECOMMENDATION		No [If no, explain in comments]	N/ A	Comments
Unconditional Approval				
Conditional Approval				
Defer until more information is obtained				
Disapprove				
CONTINUING REVIEW FREQUENCY (Regulations require continuing review must be at least every 12 months. The review period will reflect an interval appropriate to the degree of risk. More frequent review may be considered for research when the degree of risk warrants closer monitoring.)				List determined frequency:

MAJOR CONCERNS ABOUT PROTOCOL
GENERAL COMMENTS

_____ _____

Signature of Primary Reviewer Date