Zagazig University
Faculty of Medicine
Institutional Review Board
(IRB)

نموذج ٦

INSTITUTIONAL REVIEW BOARD (IRB)
PROTOCOL REVIEW CHECKLIST

Protocol No. ---------- **Date:** --- / ----- / 2012

Title of Research Protocol:

PROBLEM FRAMEWORK	Yes	No	N/A	Comments
1. Is the **title** of the research scientifically sound? (what, who, where and when)				
2. Does the **background** information and literature review justify the study?				
3. Does the **rational** justify why this study is important and needed?				
4. Is the **research question** concise and establishes the boundaries to concepts, individuals or phenomena that will be examined?				
5. Is there a need for a **hypothesis?** If yes, is it properly formulated?				
6. Is the **aim** stated?				
7. Are the **objectives** clear, well described and achievable? (SMARTER)				
METHODOLOGY	**Yes**	**No**	**N/A**	**Comments**
1. **Study Design:** is it appropriate for the research question?				
2. **Setting:** Is the Site appropriate for the type of study, geographic location specified…etc				
3. Is the type of **Population** specified? (healthy, patients, special group etc)				
4. Are **subjects included** appropriate for the research question?				
5. Are **inclusion criteria** described?				
6. Are **exclusion criteria** described?				
8. Are **withdrawal criteria** for individual subjects adequately described?				
9. Is the **sample selection and size** calculated?				
10. Are the study **process** well described? How he/she will carry out the research?	√			

11. Is there a description of the **data collection**? Tools, check lists …etc			√	
12. Are **data analysis** plans adequately described?				
13. Is the **pilot study** described?				
RISK /BENEFIT ASSESSMENT	**Yes**	**No**	**N/A**	**Comments**
1. Are there **risks** present and clearly defined?				
2. What is the **level of risk** in this study" Minimal, greater than minimal, risky, too risky"?				
3. Are plans to **monitor** and report adverse events appropriate?				
4. Are there potential **benefits** to individuals, society and if so, are they described?				
INFORMED CONSENT **Elements**	**Yes**	**No**	**N/A**	**Comments**
1. An explanation of the **purpose** of the research.				
2. A statement that it is **research**				
3. Expected **duration** of the subject's participation				
4. A description of the research **procedures** to be done				
5. Anticipated **risks**, including psychological and social, if any.				
6. Precautions taken to **minimize these risks**.				
7. Actions taken if **risks** occur.				
8. A description of possible **benefits**, if any, to the **subject** and **community**.				
9. An insurance of **confidentiality** of records identifying the subject.				
10. A statement describing any **compensation or payment** to be provided				
11. A statement describing any **compensation for risks** related to research participation.				
12. The name and contact information of a person who can provide more information about the **research project**.				
13. A statement that participation is **voluntary**, and that the participant may discontinue participation at any time.				

REVIEWER RECOMMENDATION	Yes	No	N/A	Comments
Unconditional Approval				
Conditional Approval				
Defer until more information is obtained				
Disapprove				

MAJOR CONCERNS AND GENERAL COMMENTS

Signature of Primary Reviewer **Date**