**GUIDANCE 26**

**GUIDANCE FOR PROTOCOL CONENTS**

**PREPARING A RESEARCH PROTOCOL – RU GUIDANCE ARTICLE 7**

[**https://research.rowan.edu/officeofresearch/compliance/irb/policiesguidance/index.html**](https://research.rowan.edu/officeofresearch/compliance/irb/policiesguidance/index.html)**.**

Every IRB application must be accompanied by a protocol for research. The protocol must be a summary of the research plan outlined according to factors, which the IRB considers essential for its review.

7.1 Qualifications of the Principal Investigator (PI)

7.2 Who may be the Principal Investigator?

7.3 Determining Whether Research Involves Human Subjects

7.3.1 Categories of Research under Non-Human Subject Research

7.4 Unaffiliated Investigator Agreements

7.5 Roles and Responsibilities of Principal Investigator

7.6 Additional Responsibilities of a Principal Investigator

7.7 Required Components of a Research Protocol

7.7.1 Purpose/Specific Aims

7.7.2 Background and Significance

7.7.3 Research Design and Methods

7.7.4 Duration of Study

7.7.5 Study Sites

7.7.6 Sample Size Justification

7.7.7 Subject Selection and Enrollment Considerations

7.7.8 Inclusion Criteria

7.7.9 Exclusion Criteria

7.7.10 Subject Recruitment

7.7.11 Consent Procedures

7.7.12 Subject Costs and Compensation

7.7.13 Chart Review Selection

7.7.14 Study Variables

7.7.15 Risk of Harm

7.7.16 Potential for Benefit

7.8 Data Handling and Statistical Analysis

7.9 Data and Safety Monitoring

7.10 Reporting Results

7.10.1 Individual Results

7.10.2 Aggregate Results

7.10.3 Professional Reporting

7.11 Bibliography

7.12 Additional Considerations

7.12.1 Sponsor Protocols

7.12.2 Research Involving Investigational Drugs or Devices

7.12.3 Studies involving Multiple Diseases

7.12.4 Tips on Subject Recruitment and Selection

7.12.5 Tips on Site Selection

7.12.6 Tips on Research Design

7.12.7 Obtaining a “Certificate of Confidentiality" to Protect Against Compulsory Disclosure of **Confidential Information**

 7.12.7.1 Obtaining Certification of Confidentiality for NIH and Other HHS Agencies (Non-NIH) I

 7.12.7.2 Obtaining Certification of Confidentiality for NIH-HHS Federal Funders Indent

 7.12.7.3 Obtaining Certification of Confidentiality for Non-Federal Funders Indent