RESEARCH METHODOLOGY AND ETHICS IN HEALTH SCIENCES – JUNE 28, 2018, THURSDAY SESSION

Case 1

An investigator wants to study female infant genocide is to be conducted in China. The investigator proposes a study of small, rural villages, one village selected from each of four distinct geographic areas. The investigator will go to local health care clinics and proposes to Interview women after their clinic appointment. The interviews will be taped, transcribed in the field, and then the tapes destroyed. Interviews will occur in a local health clinic. Participants will receive $50 for the interview. The investigator requests the IRB to approve a waiver of written consent given the potential risk to the respondent and the highly sensitive nature of the study. Data will be summarized by geographic area.

1. Are there any special concerns or requirements for how women should be recruited?
2. What type of consent is required, if any. Please specify your choice and why it is ethically appropriate?
3. If you were to require consent, please describe what you would include in the consent?
4. Please comment on any other ethical concerns about this research and how it is conducted

Case 2

An investigator wants to develop a model for physical and occupational therapy for persons with dementia. She proposes to videotape Alzheimer's patients living in assisted living facilities. Cameras will be placed in an unobtrusive manner (but not hidden) in public areas, such as the dining or activity rooms, and not set to track any one resident. Tapes would be analyzed qualitatively, relating degree of engagement in activities to signs of well-being, and the resulting data will be used to optimize physical/ occupational therapy for persons with Alzheimer's and other dementias. Confidentiality would be protected through use of pseudonyms when analyzing the videotapes, and then destroying the tapes after analyses are complete. The videotaping would obviously "capture" everyone in the room, and it may be difficult or impossible to obtain direct consent from every individual resident, their families, or other visitors.

1. Should the IRB allow the study to be conducted without consent, if the directors of the living facilities approve?
2. Should the subjects' families be informed that the study is taking place, even if their consent will not be sought? How about staff – should their consent be sought since it can?
3. Can the residents give consent? How would you determine that?
4. Please comment on any other ethical concerns about this research and how it is conducted

Case 3

Part 1

A 42-year-old male is brought to an emergency room unconscious with severe head trauma. The physicians want to use an investigational drug which scavenges free radicals in order to prevent further brain damage. An initial drug needs to be administered within 4-6 hours of head trauma. A second dose and third dose are given 12 and 24 hours later. If the subject recovers neuropsychological testing will be performed 1, 3 and 6 months after the injury. There is no legally authorized representative available to give "consent" at the time the subject arrives in the emergency department.

1. Can the drug be administered without informed consent? Why or why not.
2. Are there other requirements to be considered before the drug is administered?
3. If you believe the drug can be administered without consent are there any special steps that can be taken after the first dose of drug is administered.

Part 2

A study is proposed to develop a new blood substitute for paramedics to use in the field. It is a Phase III Trial called "Safety and Efficacy of a New Artificial blood substitute in Hemorrhagic Shock Following Traumatic Injuries Beginning in the Pre-Hospital Setting". The study begins enrolling/administering the blood substitute when the paramedic arrives at the injury scene and continues through ambulatory transport. When the subject arrives at the hospital the investigational blood substitute will continue to be administered up to 12 hours of inpatient hospital stay or for 6 units of the blood substitute, whichever comes first.

1. Can the drug be administered without informed consent? Why or why not.
2. Are there other requirements to be considered before the drug is administered?
3. Are then any other ethical issues that are of concern in this study

Case 4

An investigator is proposing research to study if group peer discussions is an effective method for providing educational information about sexually transmitted diseases for adolescents who are sexually active? The study population will involve adolescent between the ages of 12-18. After a regularly scheduled clinic visit the adolescent will be approached and asked if they would like to participate in a series of three one-hour group discussions that are held during three consecutive weeks. They will complete a background questionnaire which will ask demographic information, information about their sexual activity, choice of birth control, high risk behaviors, use of alcohol and illicit drugs. They will also be asked questions regarding knowledge of sexually transmitted diseases. There will be a one-year follow-up survey to see if their sexual behavior has changed and if they have shown improvement in their knowledge about sexually transmitted diseases

1. What are the consent issues?
2. Should parents be required to provide consent? Please specify why or why not
3. Are there other ethical concerns regarding this research?

Case 5

A patient with advanced melanoma has only a 5th grade education and is barely literate. She is unable to fully comprehend the research (a late Phase II study) which offers the best prospect of health benefit.

1. Could you enroll her in research?
2. If so what additional steps would you consider?
3. What if the research was to ask for an extra bone marrow biopsy for lab research (no drug intervention)? Should she be enrolled why or why not?