

SUPPLEMENTARY MATERIAL

APPENDIX 1. CASES FOR SIMULATION-BASED ACTIVITY

OBSERVATIONAL RESEARCH CASES

- Consent to communicate the case of an infant with a rare congenital disease
 - Consent to participate in a prostate screening test
 - Consent to participate providing clinical information on an analytic observational study regarding environmental exposure to pollutants
 - Consent regarding information for a verbal autopsy in the case of maternal death
 - To participate in a prospective study regarding the food environment at home and a child weight status
 - To report the clinical case of a patient with a rare tumor who underwent a successful treatment
 - To report the outcome of an elderly patient with blindness due to retinopathy
 - To include a patient's medical records for a case series regarding an emerging viral disease associated with an ongoing outbreak
 - To participate in a breast screening test for research purposes
 - To participate in a sexually transmitted diseases study of seroprevalence
 - To provide clinical records and an interview on sexual dysfunction after incomplete spinal stroke
 - To use photographs and images of rare cutaneous lesions as image-based clinical case reports and educational purposes
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ADDITIONAL CONSIDERATIONS ADDED:

- The patient is a minor
- The patient's parents are under a dispute for custody
- Elder patient with dementia
- Patient who only understands indigenous dialect
- Patients from underserved remote communities
- Minor does not want to participate even when parents do
- Patient from specific religious groups
- Patient fearing for the spouse opinion

EXPERIMENTAL RESEARCH CASES

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- To enroll in a study of a new administration vehicle of insulin (nasal spray)
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- To receive a knee prosthesis elaborated with plastic materials under experimentation
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- To enroll in an experimental pharmacologic treatment for cancer that generates hormonal dysfunction
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- To enroll in an experimental rehabilitation program after amputation of a toe in a diabetic patient
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- To participate in a clinical trial regarding a new technique of bariatric surgery
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- To enroll in a five-year cohort study of urinary tract infections in patients with congenital renal malformations
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- To participate in a drug trial regarding a pharmacologic alternative to reception of blood transfusions in patients who are programmed for hysterectomy
-
- To accept a new scheme of experimental hyperbaric oxygen therapy in a patient who refuses fasciotomy to treat compartmental syndrome in lower limb
-
- Experimental plasmapheresis procedure in a patient with pancreatitis
-
- For a Parkinson's disease experimental surgery
-
- For an experimental intervention with aromatherapy during trans-surgical period
-
- To participate providing a new unpatented formula for infants and toddlers
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CONSIDERATIONS ADDED:

- The patient has a terminal disease
- The patient's parents are under a dispute for custody
- Elder patient with dementia
- Patient who only understands indigenous dialect
- Patients from underserved remote communities
- Minor does not want to participate even when parents do
- Patient from specific religious groups
- Patient already on a clinical trial

APPENDIX 2

Student Name:

Class and generation:

Evaluator:

EVALUATION CHECKLIST FOR SIMULATION-BASED INFORMED CONSENT FOR HEALTH RESEARCH WITH HUMAN SUBJECTS.		SI	NO	N/A
1	Introduces him/herself providing his name, position and institution			
2	Adequately Identifies the individual who is in conditions to be informed and consent			
3	Informs on the nature of the study (experimental/observational) for which s/he asks for consent			
4	Informs about the main objective of the study			
5	Clearly explains the scientific and social benefits that will derive from the research			
6	Informs on the risks associated with the patient's participation (social, psychological and physical)			
7	Provides information of the alternatives to the patient's participation			
8	Ensures the voluntary nature of his participation			
9	Provides contact information and how to obtain additional data			
10	Advises on what to do if the patient change his/her mind to withdraw			
11	Provides specific information on how the identity and personal information Will be protected			
12	Specifies if the information will be used for other researches, educational or publication purposes			
13	Does not offer inadequate or unreal remuneration			
14	Informs of the main expected outcomes after treatment (when applicable)			
15	Uses adequate terminology, explaining any technical terms clearly			
16	Does not exaggerate the benefits or minimize the risks			
17	Asks for a translator in case of a foreign language patient			
18	Asks for assent from the patient if minor (when applicable)			
19	Clarifies the difference between regular medical attention and research projects			
20	If applicable, invites witnesses and provides a copy of the informed consent			
21	Opens the opportunity for a two-way dialog			
22	Answers to the questions and doubts posed by the patient or his/her family			

Does not apply (N/A)

ANNOTATIONS

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