VERSION 1
04.20.2020

ETHICS GUIDELINES ON COVID-19

Crisis-Level Hospital Care

UNIVERSITY OF THE PHILIPPINES MANILA
COVID-19 Ethics Study Group

Endorsements

Association of Respiratory Care Practitioners of the Philippines Inc (ARCPP Philippines)

Philippine Alliance of Patient Organizations (PAPO)

Philippine College of Physicians

UP-Philippine General Hospital (PGH) Department of Internal Medicine

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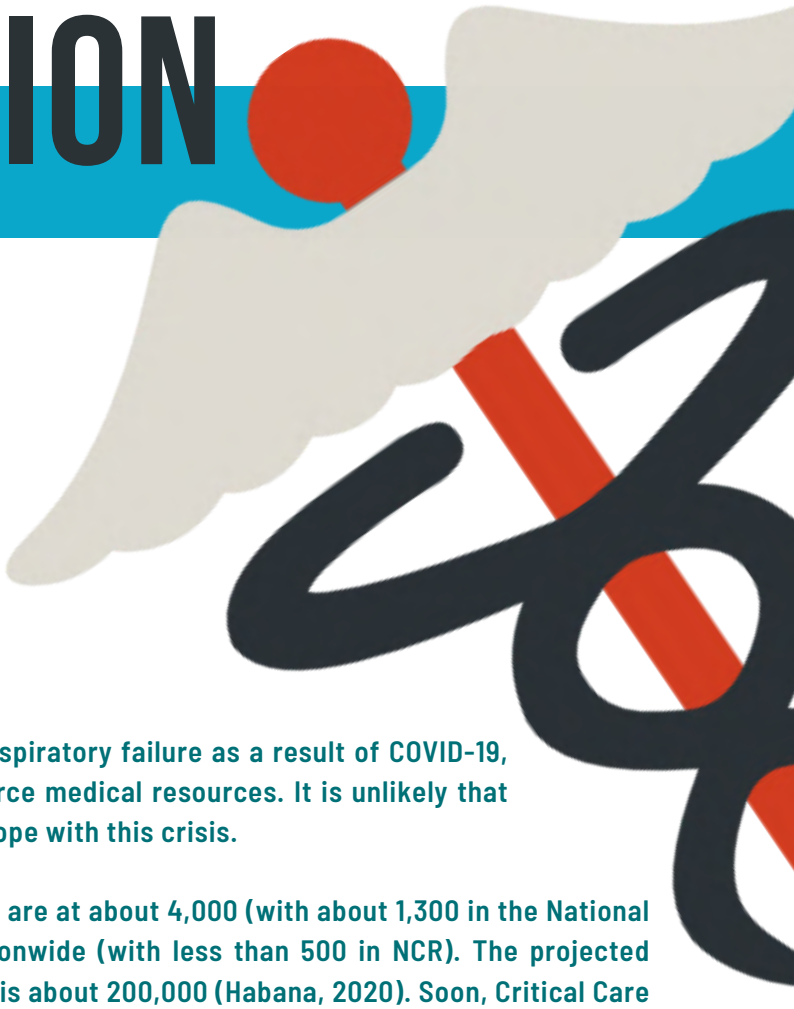
INTRODUCTION



The COVID-19 pandemic puts the country on a *war footing*. What used to be straightforward "first-come, first-served, all-available-means-should-be-used" medicine does not seem to work anymore (Cha, 2020; Mounk, 2020). Similar past experiences with SARS and influenza could rival only in likelihood of danger and medical scarcity. However, the transmissibility, tenacity, and wantonness of COVID-19 brings "extraordinary" to a whole new level, especially amidst advances in modern medicine.

More and more Filipino patients are succumbing to respiratory failure as a result of COVID-19, thus requiring ventilator support or other related scarce medical resources. It is unlikely that our current health care infrastructure will be able to cope with this crisis.

Estimates for the total number of ICU beds nationwide are at about 4,000 (with about 1,300 in the National Capital Region), and for ventilators, about 1,500 nationwide (with less than 500 in NCR). The projected demand for ventilators in the COVID-19 crisis scenario is about 200,000 (Habana, 2020). Soon, Critical Care may have to be rationed, if it is not being done already on an *ad hoc* basis. Even assuming that, say, overall ICU capacities are increased rapidly to meet demand, such a move does not necessarily guarantee an adequate standard of care for every admitted patient. It may, therefore, be inevitable at some point, or in some circumstances, that critical care can only be provided to a limited number of patients, to the detriment of those who cannot be accommodated. The difficulty of making such choices can be overwhelming for healthcare workers and for families of COVID-19 patients. As such, guides on how these decisions can be arrived at, particularly in many of the country's resource-constrained institutions, are necessary. So, what should be the *basis* of these decisions, and how can these be practicably adopted?

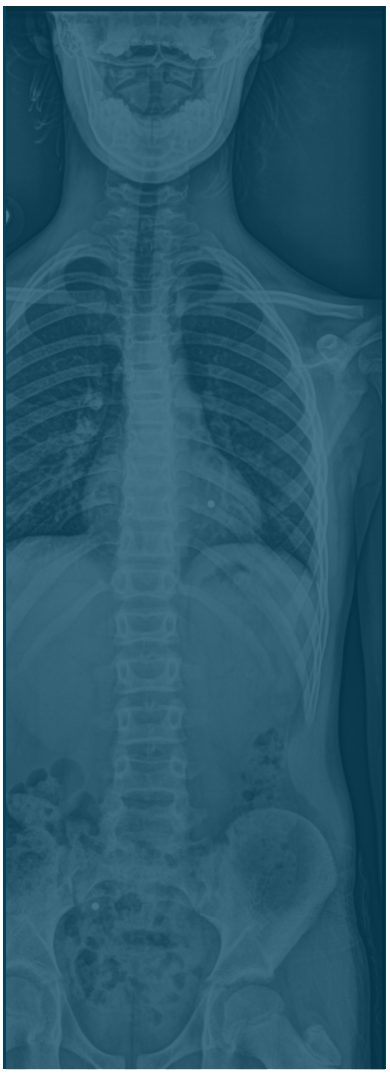
While a pre-determination of how scarce medical resource should be allocated, or rationing, is an important (if not dominant) consideration during the COVID-19 pandemic, this unprecedented crisis does not invalidate the ethical imperatives of care and relationships between care teams and patients, patients and their friends and family, between and among healthcare professionals. How should decision-makers balance between, on one hand, saving as many lives or relieving as much pain and suffering as possible, and, on the other hand, aiming for the best possible quality of life and seeing through the cases of the patients they have come to care for?

These Guidelines have been developed to provide an **ethical framework** for decision-making in crisis situations brought about by the COVID-19 pandemic.

VERSION 1. This document is evolving. Its latest 'clean' version is at ethicists.org/latest-covid-ethics.pdf. Shortcut to the current version that considers comments and suggestions from the public: upsilab.org/covid-19-ethics. Initially based on related documents and experiences, both local and international (see References below), these Guidelines have been extended to include comments and suggestions from Philippine stakeholders and colleagues. Using the Comment function of the platform, you may propose further revisions and offer discussions. Open collaboration is on-going. Feel free to contribute. Disclosure: This process of admitting public comments into the Guidelines text is part of a Project put together by a COVID-19 Ethics Study Group at the University of the Philippines for consideration for funding support from the Philippine Council for Health Research and Development (PCHRD) and the Commission on Higher Education (CHED). Other parties may also use this document for other purposes not contrary to law, public policy, and ethical standards. Feel free to adopt these Guidelines for your own institution where these might apply.

CONT



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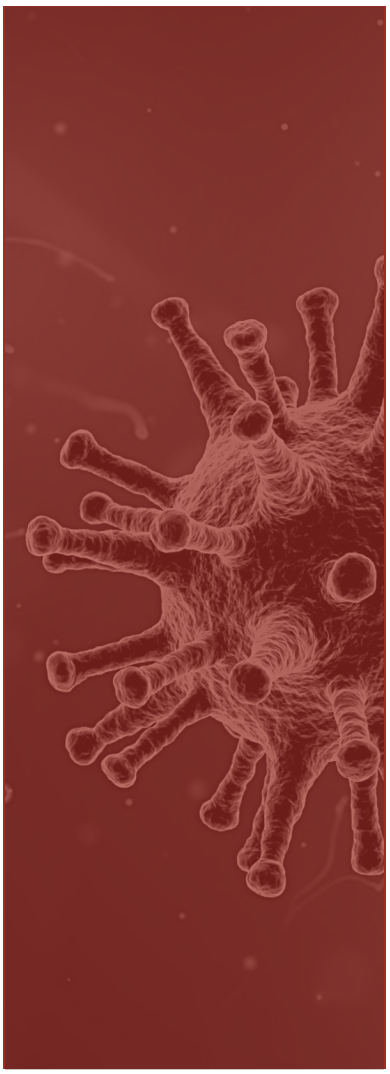
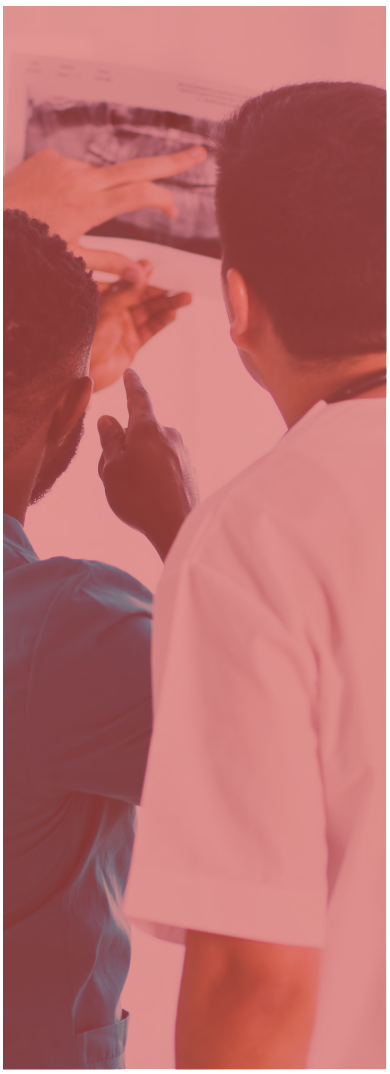
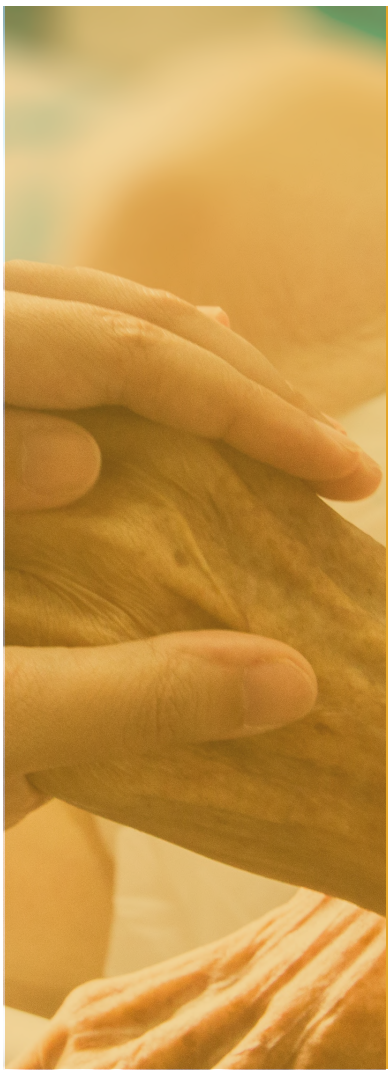


Principles

GUIDELINE 01.

Fairness in the allocation of acutely scarce resources must be pursued in all levels of healthcare. While the COVID-19 pandemic has put the country on a war footing, the allocation of healthcare resources must continue to uphold the principle that every human life is of equal worth and deserves the same level of care regardless of economic, social, religious or political position.

Differences in care and treatment can only be based on appropriate medical criteria using evidence-based clinically prognostic parameters.

Further prioritization can be based on the principles of **minimizing harm** (reducing spread of the pandemic, limiting disruption, and improving prospects of continued health care services in the time of COVID-19), of **equity** (addressing vulnerabilities of patients), and **urgency** (giving utmost attention to the safety and well-being of caregivers as well as to those who are in imminent danger of losing their lives).

In addition, **procedural fairness** is to be observed at every level of decision-making at the hospital. This means, in part, that procedures, rules, and processes are transparent and open to all, to help ensure that they are bias-free and evidence-based, and people adversely affected have an opportunity to fair hearing.

GUIDELINE 02.

The **duty to care** entails a responsibility to respect the rights of patients to autonomy, transparency, privacy, and confidentiality of personal information. Procedures for taking informed consent and advance directives shall be observed and, where appropriate, legally authorized substitute decision-makers shall be consulted.

The **duty to care** also involves prudent stewardship of acutely scarce resources. It requires prudent balancing of current patients' needs with stewardship of resources (including hospital infrastructure and personnel) for subsequent patients. Healthcare workers' (HCW) duty to care requires *flexibility* and *consistency* in an effort to provide adequate and sustained health care. This means that plans must be adaptable to changing circumstances – subject to modification and review as new medical evidence unfolds.

Whenever possible, in order to minimize undue influences and to support professional conduct, a hospital should separate triage responsibilities from the provision of direct care by HCWs, as well as the measures meant for group benefits from the care of individual patients. Those who have triage assignments should not *simultaneously* be the ones providing direct care.

Admission Triage

03

GUIDELINE 03.

Facility administrators should coordinate with their neighboring or network hospitals and ascertain current relative capacities. The frontline staff must be periodically informed of the current operational capacity and corresponding admission triage status of the hospital as well as of available inter-hospital referral arrangements.

GUIDELINE 04.

All patients, whether or not afflicted with COVID-19, upon arrival at the hospital, should be adequately assessed by the designated qualified personnel. The following clinical management approaches are recommended for respective patient circumstances:

a) If, based on current clinical guidelines, the patient is suitable for admission but is beyond the hospital's capacity for the corresponding care requirements, the patient should be referred to another facility.

b) If a patient, due to the severity of the condition, is anticipated to require resuscitation and subsequent ICU admission, then:

i) If capable, hospital personnel should appraise the patient, family member, or substitute decision-maker regarding the hospital's critical care allocation policy, and proceed only with resuscitation if such is acceptable with the patient or designated substitute decision-maker;

ii) If the hospital or its personnel are not equipped for resuscitation, or will be unable to further handle critical patients, then no resuscitation measures are to be initiated.

c) Applicable referral and palliative care options should be provided for appropriate cases.

04

Communication of Care

05

GUIDELINE 05.

At the time of admission, the patient or family member should be oriented, and the conforme be documented, on the following matters:

a) Nature of the illness and likelihood of unfavorable course and outcome;

b) Viewing, visitation, or updates on restrictions;

c) Possibility that drugs not proven to be effective against the condition may be used (See: Informed consent template for off-label drug use);

d) Possibility that some interventions may not be provided if, due to the prevailing circumstances, these become unavailable or be for the use only of patients who fulfill the corresponding triage criteria of the hospital;

e) Statement that anonymized information regarding the patient and treatment will be collected for research purposes; and,

f) Statement that information regarding possible close contacts will be collected but kept confidential.

GUIDELINE 06.

Advanced care planning should be initiated at the earliest appropriate time and preferably even before hospital admission. The patient shall be encouraged to accomplish an Advance Directive, a template for which is provided.

A written or documented Advance Directive may contain the following elements:

(a) The patient's (or the substitute decision-maker's) awareness of the situation;

(b) Medical interventions that should not be administered;

(c) Medical treatments that should be considered;

(d) Consent (or non-consent) to participate in research that may or may not directly benefit the patient;

(e) Consent (or non-consent) to resuscitation measures; and,

(f) Instructions for palliative or terminal care.

06

07

GUIDELINE 07.

Should the patient be incapable of attending to the Advance Directive, then a qualified relation or representative must be requested to consider and accomplish the Substitute Decision-Maker form, a template for which is also provided. (See: Substitute Decision-Maker in COVID-19 Hospitalization - English | Filipino)

08

GUIDELINE 08.

The hospital must designate a unit or someone from the healthcare team to at least relay the patient's status to the patient's relatives, should this be the stated preference of the patient.

GUIDELINE 09.

In the course of the patient's confinement, hospital or care facility arrangements should be made for remote communication between patients and their relatives. The presence of family and friends when death of the patient seems inevitable ought to be allowed to the extent that it does not increase risk for them or HCWs to contract the disease.

09

Therapeutic Interventions

10

GUIDELINE 10.

Given the concurrent resource capacities of the hospital, all necessary supportive and nursing care shall be provided to all patients, in keeping with the standard of care.

11

GUIDELINE 11.

The use or administration of off-label pharmaceuticals or other non-standard interventions (also known as compassionate use, expanded drug access, or monitored emergency use of unregistered and experimental interventions (MEURI)) for non-research purposes may be permissible under the following circumstances:

a) Indications for the non-standard intervention exist (i.e., absence of satisfactory or better alternative, risk posed by the disease is higher than that attributable to the treatment, and use will not interfere with the conduct of clinical trials);

b) A designated hospital authority exists to review, approve, and monitor the use of the drug or intervention, and;

c) Informed consent is secured from the concerned patients. Should such not be possible for valid reasons, then alternative means may be undertaken (e.g., substitute decision-maker, retroactive, etc.) as may be acceptable with the hospital authority.

ICU Allocation

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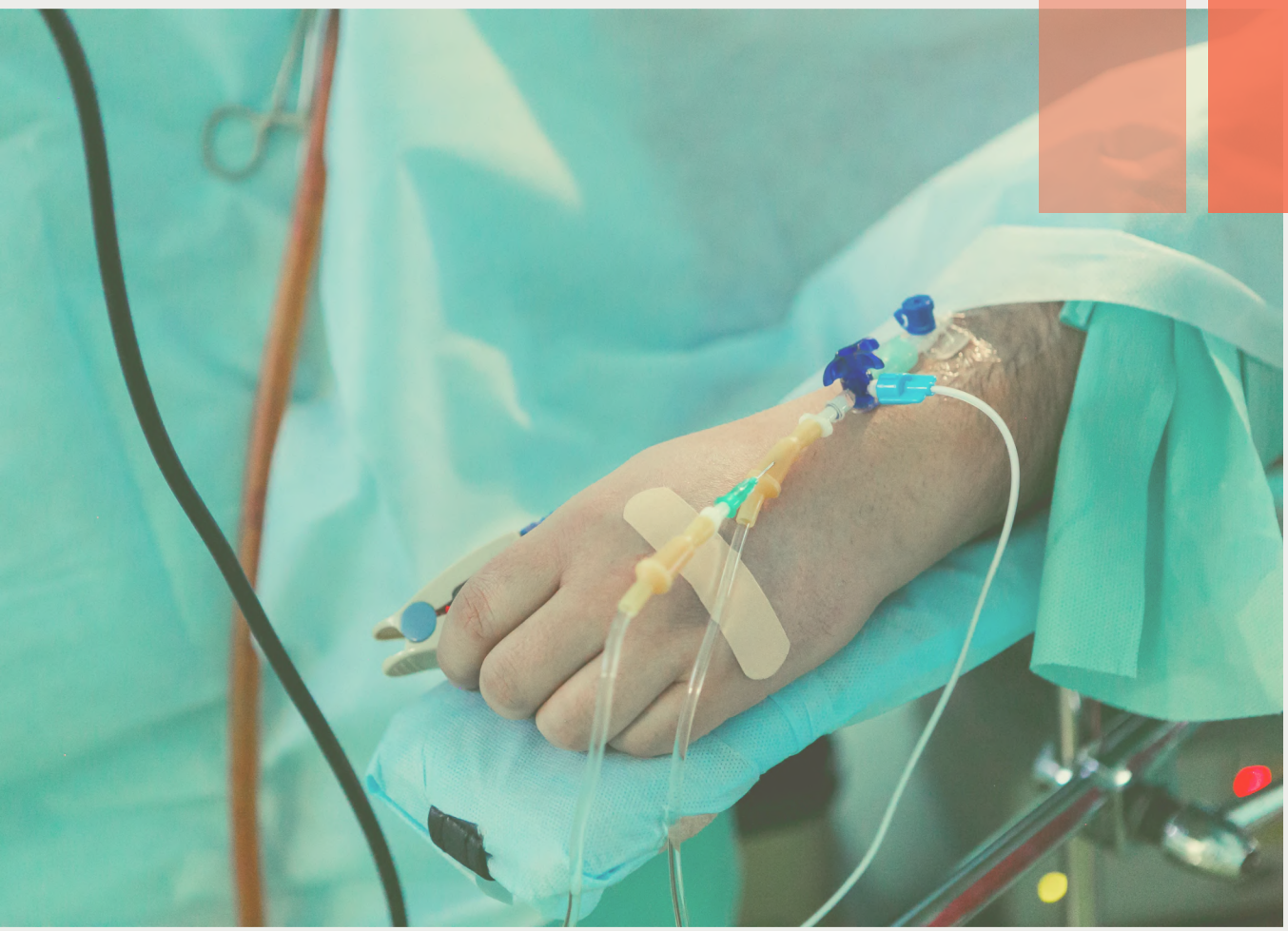
GUIDELINE 12.

Hospitals should adopt robust criteria for ICU admissions, and favor particularly those who have acute, reversible conditions. The patient's Advance Directive or Substitute Decision-Maker's documented preferences for withholding or withdrawal of specific interventions are to be followed.



GUIDELINE 13.

Due to current or anticipated excessive demand for ventilator support for severely ill COVID-19 patients, an objective allocation system for this intervention should be developed or adopted by the hospital, possibly through the Patient Liaison Committee or similar body. The criteria should be consistently and transparently implemented and regularly reviewed by the hospital.

a) The allocation system should be based on clinically driven prognostic criteria. Patients' status and the concurrent appropriateness of ventilator allocation should be assessed periodically.

b) A documentation and reporting system should be established to enable the attending physicians to rapidly and accurately communicate the patient's parameters to the Patient Liaison Committee.

c) The said Committee should expeditiously deliberate and decide on withholding or withdrawing ventilator support for any given case, based primarily on the criteria-based assessments of the attending physicians.

d) The Committee's decision is final, unless there is a change in the patient's status that may signify an altered prognosis – for which an appeal can be lodged by the patient's attending physician or relatives.

e) Patients who are not afforded ventilator access are to be given alternative therapies, including palliative care. Respiratory support by "ambu bagging" is not an acceptable option.

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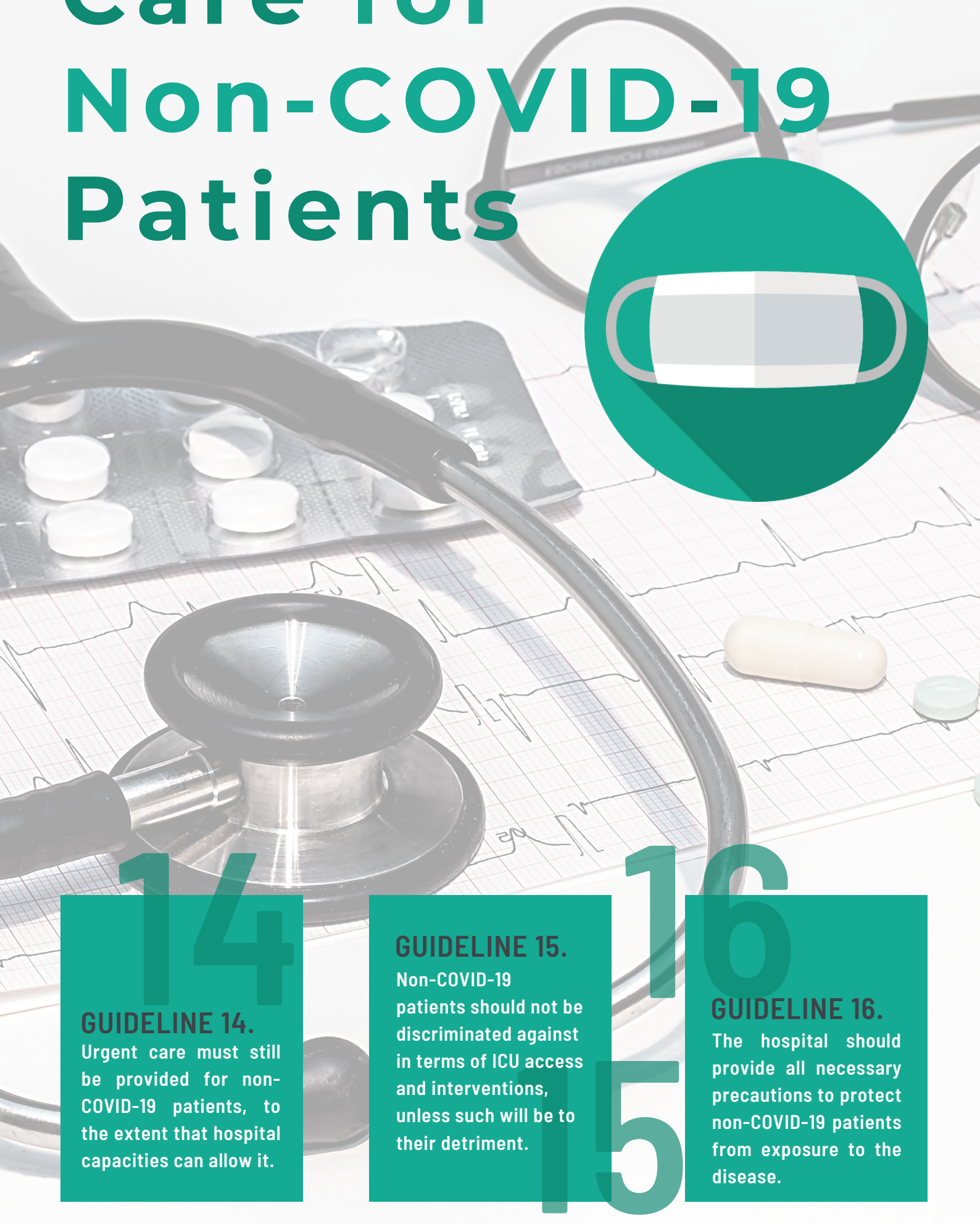
Care for Non-COVID-19 Patients



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GUIDELINE 14.

Urgent care must still be provided for non-COVID-19 patients, to the extent that hospital capacities can allow it.

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GUIDELINE 15.

Non-COVID-19 patients should not be discriminated against in terms of ICU access and interventions, unless such will be to their detriment.

16

GUIDELINE 16.

The hospital should provide all necessary precautions to protect non-COVID-19 patients from exposure to the disease.

Information Management

17

GUIDELINE 17.

HCWs and public health authorities shall collect or process personal data necessary in providing care, contact tracing and for other public health purposes, while maintaining the confidentiality of COVID-19 patients.

18

GUIDELINE 18.

Insofar as they relate to COVID-19 hospitalization, institutional and professional data sharing arrangements and commitments by the health facility shall be disclosed to COVID-19 patients and HCWs.

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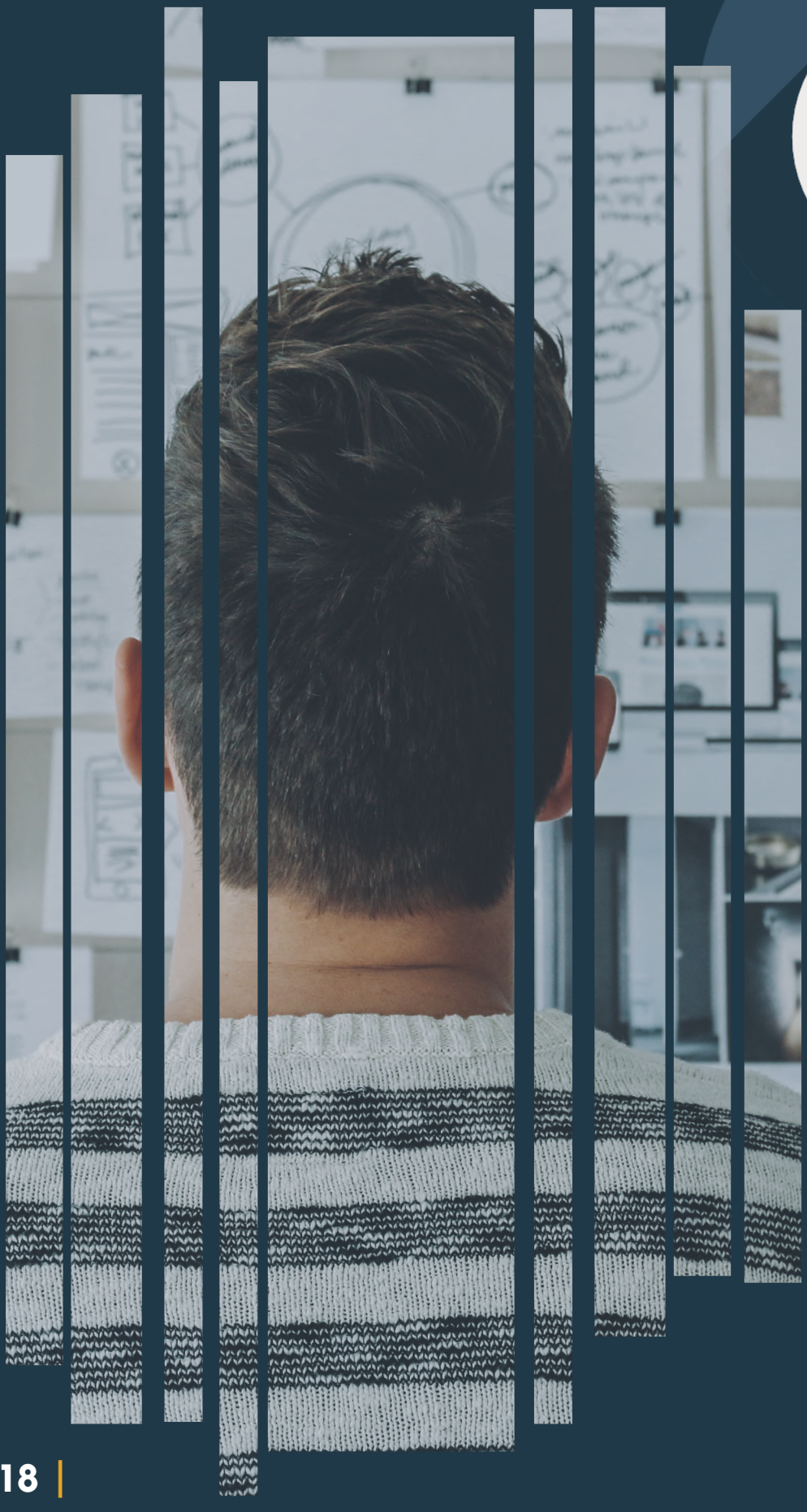
GUIDELINE 19.

The personal information of persons identified through contact tracing should be similarly safeguarded. Measures should be taken to address potential stigmatization.



Research

GUIDELINE 20.

Priority should be given to research related to improving care and outcomes as well as preventing disease resurgence.

GUIDELINE 21.

The design and conduct of research should be appropriate to the situation and should not hamper service delivery. Local resources and capacities permitting, randomized controlled trials for therapeutic interventions are preferred over other methods.

GUIDELINE 22.

With a duly obtained informed consent, the use of non-standard interventions or medication should be discussed with the patient, carefully outlining their potential adverse reactions and the possible clinical benefits while understanding the patient's vulnerabilities. For cases where informed consent may be difficult to obtain, especially for critically ill patients, alternative methods for consent may be utilized, such as: substitute decision-maker's consent, deferred patient consent, deferred substitute decision-maker's consent, objection to participation, and waived consent. Well-documented verbal, telephone or electronic consent from the substitute decision-maker can also be considered.

GUIDELINE 23.

Given the exigencies of the situation, research protocol formulation should be expedited. A centralized or networked technical and research ethics review will be in line with this. No research should be undertaken without the approval of appropriate bodies.

Personnel Rights and Obligations

GUIDELINE 24.

Health authorities and hospital administrators have the following obligations with regard to HCWs exposed to danger and contagion:

a) Implement measures to minimize risk of exposure, including the provision of personal protective equipment (PPE) and safe working spaces;

b) Provide policies on modification of standard use of PPE in cases of crisis capacity;

c) Provide extra remuneration and, if needed, proper accommodations;

d) Provide access to health care;

e) Provide psychosocial support such as opportunities for self-care, team debriefing, and professional consultations, and implement measures to monitor burnout and distress;

f) Provide assistance to the HCW's family; and,

g) Initiate programs to facilitate community integration.

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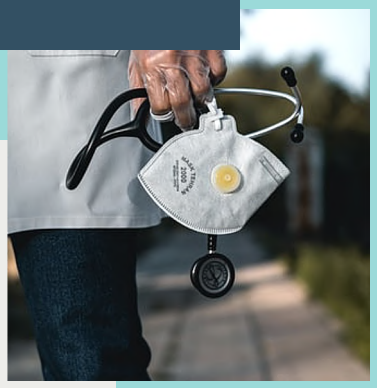
GUIDELINE 25.

The duty to care for the patient extends to observing measures that do not compromise the caregiver's safety. When PPE is inadequate, an HCW may choose to be excluded from contact with suspected or confirmed COVID-19 cases but may be expected to perform non-frontline duties.



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GUIDELINE 26.

HCWs have additional obligations during the pandemic, namely to:

a) Participate in reporting and surveillance activities;

b) Provide accurate information to the public; and,

c) Avoid exploitation of patients or their family.

Working Committees

GUIDELINE 27.

The hospital's **Ethics Committee**, together with other concerned officials or units, should review these Guidelines and adopt what will be appropriate for local circumstances.

GUIDELINE 28.

The hospital may constitute a **Patient Liaison Committee** (or an equivalent group) for purposes listed below. The hospital's Ethics Committee may also be mandated to perform the same functions. These functions include:

a) Setting the allocation criteria as well as deliberate and decide on the ICU access of patients;

b) Communicating with patients' families regarding the status of patients and, if resources and circumstances allow, provide the means by which families can remotely communicate with patients; and

c) Closely coordinating with the hospital body tasked with the overall crisis response in order to be able to adjust the allocation criteria to the prevailing situation and resources.

GUIDELINE 29.

The hospital may consider realigning the functions of the **Therapeutic Committee** to allow oversight on the use of off-label pharmaceuticals for non-research purposes.

Post-Mortem Care

GUIDELINE 30.

In caring for the bodies of those who have expired due to COVID-19, personal and religious preferences may be overridden by public health and safety concerns. Cremation within 12 hours after death is recommended.

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ERENCES

APPENDIX A

Advance Directive Template in COVID-19 Hospitalization

I, _____, of legal age, from _____, do hereby state that:
[FULL NAME] *[ADDRESS]*

- **Awareness of the situation.** The health care team has explained to me the gravity of my medical condition and the possibility that this may worsen, despite their best efforts. I understand that point may be reached, in the coming hours or days, wherein there is no reasonable expectation of a full recovery regardless of the use of aggressive medical interventions. While I am still of sound mind and have the capacity to decide for myself, I am now signifying my personal preferences on the medical interventions that may be undertaken for me. I understand that, while I am still able communicate, and if I so desire, I can immediately express my wish to change any of these indicated preferences.

- **Substitute health care-related decisions.** Should I become unable to communicate, I wish_____, _____,
[NAME OF KIN/ LEGALLY ACCEPTABLE REPRESENTATIVE/ SUBSTITUTE DECISION-MAKER] *[RELATION]*

  to make health care-related decisions for me. He/She can be reached through _____.
[CONTACT NUMBER]

- **Medical treatments / Interventions.** I wish to state my personal decision on the following medical treatments/interventions, should I show signs of rapid deterioration and my health care team determine that my illness is irreversible and my life is limited to a short period of time. My personal decisions on the following medical treatments/ interventions are as follows:

[1] Advance directives should be discussed the earliest appropriate time in the course of disease or treatment.

Shortcut to this document: ethicists.org/advancedirective. This drafting exercise is part of "A Project Proposal to Rapidly Develop a Draft Set of Ethics Guidelines on COVID-19 Hospital Care". The Guidelines document being written is found at: upsilab.org/covid-19-ethics. Using the Comment function of this platform, you may propose revisions and offer discussions. Crowdsourcing, open collaboration going on. Feel free to contribute. Related drafting exercise: Informed Consent Template for Off-label Use of Medications or Investigational Drugs for COVID-19. Feel free to adopt this template at your own institution where it might be useful. A Filipino version is also available.

APPENDIX A

Cardiopulmonary Resuscitation (CPR)

An emergency lifesaving procedure performed when the heart stops beating

- Includes the following: manual or automated chest compressions and/or the application of electric shocks to jump start my heart in case of abnormal rhythms and cardiac arrest.

[ ] I am allowing CPR in case of cardiopulmonary arrest.	**[ ]** I **DO NOT** allow CPR.

Intubation and Mechanical Ventilation

An intervention wherein a machine pumps air into my lungs and breathes for me through a tube placed in my mouth into my windpipe (called an endotracheal tube) to help me breathe when I will have a hard time breathing. I will not be able to talk nor eat through my mouth while I am on the machine.

[ ] I am allowing the placement of the endotracheal tube and ventilator support.	**[ ]** I **DO NOT** allow the placement of the endotracheal tube and ventilator on myself. **[ ]** I wish to **DISCONTINUE** the use of the ventilator and I wish to have the endotracheal tube removed, after a thorough discussion with my loved ones and the authorized hospital representatives about mechanical support.

Vasopressor / Inotropic Support

Medicines given to raise my low blood pressure and/or improve the contraction of my heart

[ ] I am allowing the use of these medications.	**[ ]** I **DO NOT** allow these medications. **[ ]** I wish to **DISCONTINUE** these medications.

Dialysis

This machine temporarily cleans my blood of poisonous substances if my kidneys stop working. In order for dialysis to be done, a small tube will be inserted through one of my large veins for connection to the machine.

[ ] I am allowing dialysis.	**[ ]** I **DO NOT** allow dialysis. **[ ]** I wish to **DISCONTINUE** dialysis.

Blood Transfusion

This process will add blood in my veins.

[ ] I am allowing this blood transfusion.	**[ ]** I **DO NOT** allow blood transfusion. **[ ]** I wish to **DISCONTINUE** blood transfusion.

APPENDIX A

I understand that this directive can be revoked by me or any of my substitute health care decision-makers at any time by any means, as my needs may change.

I grant permission for this document to be reviewed by all persons directly involved in my care and well-being.

I release the hospital _____, the attending physician, and
[NAME OF HOSPITAL]

the staff from any liability related to my preferences indicated above.

Respectfully yours,

Printed Name and Signature of **Patient**
Date and time signed:

Explained by:

Printed Name and Signature of **Attending Physician**
Date and time signed:

Witnessed by:

Printed Name and Signature of **Witness**
Date and time signed:

APPENDIX B

Substitute Decision-Maker in COVID-19 Hospitalization

I, _____, of legal age, from _____,
[NAME OF SUBSTITUTE DECISION-MAKER] *[ADDRESS]*

am the SUBSTITUTE HEALTH CARE-RELATED DECISION-MAKER for _____ by virtue of being the _____
[NAME OF PATIENT] *[STATE NATURE OF RELATIONSHIP TO PATIENT]*

I can be contacted through _____.
[CONTACT NUMBER OF SUBSTITUTE DECISION-MAKER]

I do hereby state that:

- **Awareness of the situation.** The health care team has explained to me the gravity of my patient's medical condition and the possibility that this may worsen, despite their best efforts. I **understand** that a point may be reached, in the coming hours or days, wherein there is no reasonable expectation of a full recovery regardless of the use of aggressive medical interventions. I understand that if I may wish to change any of these indicated preferences, I may do so at any time or any means and upon discussion with the hospital's representatives on these issues.

- **Medical treatments / Interventions.** On behalf of my patient, I allow my patient to receive the following medical treatments/interventions should the need arise:

[1] Advance directives should be discussed the earliest appropriate time in the course of disease or treatment. A Filipino version is also available.

This drafting exercise is part of "A Project Proposal to Rapidly Develop a Draft Set of Ethics Guidelines on COVID-19 Hospital Care". The Guidelines document being written is found at: upsilab.org/covid-19-ethics. Using the Comment function of this platform, you may propose revisions and offer discussions. Crowdsourcing, open collaboration going on. Feel free to contribute. Related drafting exercise: Informed Consent Template for Off-label Use of Medications or Investigational Drugs for COVID-19. Feel free to adopt this template at your own institution where it might be useful.

APPENDIX B

<table>
<tr><td colspan="2"><u>Cardiopulmonary Resuscitation (CPR)</u>
An emergency lifesaving procedure performed when the heart stops beating
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<tr><td>[ ] I am allowing CPR in case of cardiopulmonary arrest of my patient.</td><td>[ ] I DO NOT allow CPR.</td></tr>
<tr><td colspan="2"><u>Intubation and Mechanical Ventilation</u>
An intervention wherein a machine pumps air into my patient's lungs and breathes for my patient through a tube placed in the mouth into the windpipe (called an endotracheal tube) to help him/her breathe when he/she will have a hard time breathing. My patient will not be able to talk nor eat through the mouth while on the machine.</td></tr>
<tr><td>[ ] I am allowing the placement of the endotracheal tube and ventilator support on my patient.</td><td>[ ] I DO NOT allow the placement of the endotracheal tube and ventilator.
[ ] I wish to have the endotracheal tube REMOVED and to DISCONTINUE the use of the ventilator on my patient. These wishes have been made after a thorough discussion with the other loved ones of my patient and authorized hospital representatives.</td></tr>
<tr><td colspan="2"><u>Vasopressor / Inotropic Support</u>
Medicines given to raise the low blood pressure and/or improve the contraction of his/her heart</td></tr>
<tr><td>[ ] I am allowing the use of these medications on my patient.</td><td>[ ] I DO NOT allow these medications.
[ ] I wish to have these medications DISCONTINUED for my patient.</td></tr>
<tr><td colspan="2"><u>Dialysis</u>
This machine temporarily cleans the blood of poisonous substances if the kidneys stop working. In order for dialysis to be done, a small tube will be inserted through one of the large veins of my patient for connection to the machine.</td></tr>
<tr><td>[ ] I am allowing dialysis to be done on my patient.</td><td>[ ] I DO NOT allow dialysis.
[ ] I wish to DISCONTINUE dialysis on my patient.</td></tr>
<tr><td colspan="2"><u>Blood Transfusion</u>
This process will add blood in the veins.</td></tr>
<tr><td>[ ] I am allowing blood transfusion.</td><td>[ ] I DO NOT allow blood transfusion.
[ ] I wish to DISCONTINUE blood transfusion on my patient.</td></tr>
</table>

APPENDIX B

I understand that this directive can be revoked by me or by my patient at any time by any means as the needs of my patient may change.

I grant permission for this form to be reviewed by all persons directly involved in his/her care and well-being.

I therefore release the hospital _____, the attending physician,
[NAME OF HOSPITAL]

and the staff from any liability related to my refusal of the intervention/s indicated above.

Respectfully yours,

Printed Name and Signature of **Substitute Decision-Maker**
Date and time signed:

Explained by:

Printed Name and Signature of **Attending Physician**
Date and time signed:

Witnessed by:

Printed Name and Signature of **Witness**
Date and time signed:

APPENDIX C

Informed Consent Template for Off-Label Use of Medications or Investigational Drugs for COVID-19

I, _____, of legal age, from _____, do hereby state that:
[FULL NAME] *[ADDRESS]*

- **Awareness of the situation.**
  - The care team has explained to me the nature and gravity of my COVID-19 illness, which presently has no standard therapy.
  - I understand that drugs approved, or labelled, by the Food and Drug Association are for use only for specified conditions for which their safety and effectiveness have been established.
  - I understand that due to the, as yet, not well-defined nature and behavior of the COVID-19 virus, physicians may have to use drugs on a off-label basis, as their effectivity for this disease has not been fully established

- **Substitute health care-related decisions.** Should I become unable to communicate in the course of my care, my substitute decision-maker will continue making the decisions for me.

- **Purpose of the off-label drug.**
  - The care team has informed me that the use of these drugs are based on best available scientific evidence and that records of their use and effects will be maintained.
  - I have been informed that the off-label use of the drugs for my condition may be given either to control the infection or treat its complications.

[1] Reworked from PSMID CPGs for COVID-19 2020, v2.1 Appendix D: Informed Consent Template (if no clinical trial is available) https://www.psmid.org/cpg-for-covid-19-ver-2-1-as-of-march-31-2020/. A Filipino version is also available.

Shortcut to this document: ethicists.org/covidconsent. This drafting exercise is part of "A Project Proposal to Rapidly Develop a Draft Set of Ethics Guidelines on COVID-19 Hospital Care". The Guidelines document being written is found here: upsilab.org/covid-19-ethics . Using the Comment function of this platform, you may propose revisions and offer discussions. Crowdsourcing, open collaboration going on. Feel free to contribute. Related drafting exercise: Advance Directive Template in COVID-19 Hospitalization. Feel free to adopt this template at your own institution where it might be useful.

- **Complications and side effects of the off-label drugs.**
  - I understand that apart from the possible benefits, there are risks and I may experience side effects of the therapy. I understand that this therapy may help me but unintended side effects, even death, may occur.
  - The care team has answered all my questions concerning the proposed therapy. If I have more questions about my therapy, I can contact _____.
    [NAME OF CARE TEAM | CONTACT]
  - I also understand that the medical team will exert all caution to prevent complications from happening, or treat these accordingly should these happen.
  - I am willing to accept the potential risks that my physician has discussed with me
  - I acknowledge that there may be other unknown risks and that the long-term effects and risks of these drugs used under these conditions are not known.

- **Rights as a patient.**
  - I know that I am free to withdraw my consent to this therapy at any time, and it will not be taken against me, nor am I expected to provide any explanation whatsoever.
  - If I wish to withdraw my consent, I will contact my care team immediately.
  - Details of my medical treatment will be made available only to authorized representatives of the hospital, FDA, and related government agencies. These details will be made anonymous if used for research purposes and a separate informed consent will be secured from me before I am included in a research study.

Printed Name and Signature of **Patient**
Date and time signed:

Printed Name and Signature of **Witness**
Date and time signed:

Printed Name and Signature of **Healthcare Team Representative**
Date and time signed:

APPENDIX D

Substitute Decision-Maker's Consent Template for Off-Label Use of Medications or Investigational Drugs for COVID-19

I, _____, of legal age, from _____,
[NAME OF SUBSTITUTE DECISION-MAKER] *[ADDRESS]*

am the SUBSTITUTE HEALTH CARE-RELATED DECISION-MAKER for _____ by virtue of being the _____
[NAME OF PATIENT] *[STATE NATURE OF RELATIONSHIP TO PATIENT]*

I can be contacted through _____.
[CONTACT NUMBER OF SUBSTITUTE DECISION-MAKER]

I do hereby state that:

- **Awareness of the situation.**
  - The care team has explained to me the nature and gravity of my patient's COVID-19 illness, which presently has no standard therapy. I understand that due to the, as yet, not well-defined nature and behavior of the COVID-19 virus, they are offering to treat my patient with _____.
    [NAME OF MEDICINE/DEVICE/BIOLOGIC]

    I understand that this is "off-label" and experimental because its effectivity for this disease has not been fully established and the FDA has not yet approved it for COVID-19 treatment.

[1] Reworked from PSMID CPGs for COVID-19 2020, v2.1 Appendix D: Informed Consent Template (if no clinical trial is available) https://www.psmid.org/cpg-for-covid-19-ver-2-1-as-of-march-31-2020/. A Filipino version is also available.

Shortcut to this document: ethicists.org/covidconsent. This drafting exercise is part of "A Project Proposal to Rapidly Develop a Draft Set of Ethics Guidelines on COVID-19 Hospital Care". The Guidelines document being written is found here: upsilab.org/covid-19-ethics. Using the Comment function of this platform, you may propose revisions and offer discussions. Crowdsourcing, open collaboration going on. Feel free to contribute. Related drafting exercise: Advance Directive Template in COVID-19 Hospitalization. Feel free to adopt this template at your own institution where it might be useful.

APPENDIX D

- **Important information about the experimental therapy for COVID-19**
  - The care team has explained to me the foreseen benefits, complications, and side effects of the therapy. I was informed that the goal of the therapy is to _____. I understand that this therapy may improve the condition of
  [GOAL OF THERAPY]

    my patient; worsen my patient's illness; bring about unintended side effects; have no effect at all; or cause the death of my patient. I have been told that my patient will be treated with this therapy until _____. The care team has
    [DATE]

    answered all my questions concerning the proposed therapy. If I have more questions about my patient's therapy, I can contact _____.
    [NAME OF CARE TEAM CONTACT]

- **Rights of my patient**
  - I know that I am free to withdraw my consent to my patient's therapy at any time, and it will not be taken against me nor am I expected to provide any explanation whatsoever. If I wish to withdraw my consent, I will contact my patient's care team immediately. Details of my patient's medical treatment will be made available only to authorized representatives of the hospital, FDA, and related government agencies. These details will be made anonymous if used for research purposes and a separate informed consent will be secured from me before I am included in a research study.

Printed Name and Signature of **Substitute Decision-Maker**
Date and time signed:

Printed Name and Signature of **Witness**
Date and time signed:

Printed Name and Signature of **Healthcare Team Representative**
Date and time signed:

FILIPINO VERSIONS

Click the arrows below to access the corresponding documents.

Apendiks A

Paunang Tagubilin Para sa
Pagkakaospital Dahil sa COVID-19

Apendiks B

Paunang Tagubilin ng Kinatawan ng
Pasyenteng Nasa Ospital Dahil sa COVID-19

Apendiks C

Pahintulot sa Off-label na Paggamit ng
mga Gamot o Eksperimentong Paggamot
para sa COVID-19

Apendiks D

Pahintulot ng Kinatawan sa Off-label na
Paggamit ng mga Gamot o Eksperimentong
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PROJECT ACTIVITIES

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upsilab.org/covid-19-ethics

Public Comments

03 APRIL 2020, 9-11AM

ONLINE SESSION

Stakeholders Conference on the Draft Ethics Guidelines on COVID-19 Hospital Care

08 APRIL 2020, 1PM

ONLINE SESSION

Consultation with Frontline Healthcare Workers

13 APRIL 2020, 1PM

ONLINE SESSION

Conference on the Ethics Guidelines on COVID-19 Hospital Care (V1)
Proceedings: youtu.be/FTB1wFMnQDw

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"[T]he Ethics Guidelines on COVID-19 Crisis-Level Hospital Care with the accompanying slide presentation, [is] an essential resource in guiding hospitals to navigate the complicated ethical issues surrounding the crisis brought about by the COVID-19 Pandemic.

This can serve as a template for hospitals to pattern their management set-up to address ethical issues concerning the entire healthcare system and the patients under its care. It is very comprehensive and the discussions are detailed but simple and easy to follow."

SUSAN P. AÑONUEVO-DELA RAMA, M.D., FPCP
Chair, Committee on Ethics 2019-2020
Philippine College of Physicians

"The Guidelines provide "handles on how to provide appropriate and compassionate patient care in times of crisis."

Maria Fatima Garcia-Lorenzo
President
Philippine Alliance of Patient Organizations

"We had the privilege to represent, actively participate, engage and provide information to this much needed document for each one of us, especially those in the frontline. Today's pandemic is unprecedented. Despite our challenges and limitations, what better way to perform our duties and responsibilities—our chosen vocation, than to arm ourselves with the best yet ethical practice of profession."

Cesar G. Bugaoisan Jr.
Chairman of the Board of Trustees
Association of Respiratory Care Practitioners of the Philippines Inc. (ARCPP Philippines)