## INSTITUTIONAL ETHICS COMMITTEE, NDCH

### Guidelines to Be Followed While Designing Consent Form

Dear Principal Investigator,

To help you process your research protocol faster, we are providing some elements that we recommend should be there in the informed consent & participant information document. Before you submit the protocol for ethical clearance we strongly urge you to build a comprehensive informed consent and participant information document.

**A well constructed informed consent & participant information document will ensure that:**

1. The participant will be provided enough information (including study title & PI name)
2. This will be provided in a language that he/she understands
3. The participant will be given adequate time to understand the implications of consenting
4. Opportunity will be given to ask questions from the PI or a member of the study team
5. Some method of assessing the comprehension of the participant will be undertaken
6. Participant's consent is voluntary and free of coercion
7. Option to refuse is offered, without comprising patient rights
8. Option to voluntarily withdraw at any stage of the research, after initially agreeing without compromising rights
9. Participant will get to retain one copy of the consent form *OR* one copy of the participant information sheet
10. Maintaining privacy of the participant and confidentiality of the data
11. Permission to publish the data while protecting privacy and confidentiality
12. The PI or a study team member will be available for clarification with adequate contact details
13. There is a place on the form for signature, name and date for the participant and/or legally authorized representative and a study team member
14. There is a place on the form for name, date and signature of an independent witness, in case the participant is illiterate or unable to sign
15. Sample of the informed consent document is provided in a local language
16. If treatment is offered to the participants, then alternate methods of treatment available must be explained to the participants.

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**Informed Consent Process:**

Obtaining valid informed consent in humanitarian emergencies such as COVID-19 is a challenge due to practical difficulties in reaching out to a patient, who may be in a COVID ward, isolation or quarantine facility. In addition, the decisional capacity of the hospitalised patient with moderate or critical disease condition would be very low and it may not be possible to differentiate between reliefs offered and research components.

**Informed consent is a continuous process involving three main components – providing relevant information, ensuring competence, ensuring comprehension and voluntariness.**

| Elements of an ICD | Additional elements (optional) |
|---|---|
| 1. Statement mentioning that it is research | 1. Alternative procedures or treatment |
| 2. Purpose of research and methods | 2. Insurance coverage |
| 3. Duration, frequency, methods | 3. Possible stigmatizing condition |
| 4. Benefits to participant, community or others | 4. Biological material and data, including |
| 5. Foreseeable risks, discomfort or inconvenience | i. Current and future uses |
| 6. Confidentiality of records | ii. Period of storage, secondary use, sharing |
| 7. Payment/reimbursement for participation | iii. Right to prevent use of biological sample |
| 8. Treatment and/or compensation for injury | iv. Provisions to safeguard confidentiality |
| 9. Freedom to participate/withdraw | v. Post-research plan/benefit sharing |
| 10. Identity of research team and contact persons | vi. Publication plan/photographs/pedigrees |

Needful procedure be followed as discussed in National ethical guidelines for involving children (assent) or legally authorized representative (LAR) in case a participant is incompetent (medically or legally), illiterate participant/LAR should be witnessed by an impartial literate witness.

Broad consent with an individual informed opt-out option may be used for research on residual clinical samples.

**The Informed Consent Document (ICD) has two parts – patient/participant information sheet (PIS) and the informed consent form (ICF) and can be prepared preferably utilizing electronic formats or plan methods to obtain consent maintaining adequate social distancing**.

**Electronic Consent:**

In light of COVID-19 infection control measures, the alternative procedures to avoid direct interaction with the patient in isolation must be explored.

Technology should be utilized to prepare interactive formats and using electronic tools such as text, graphics, audio, video, podcasts, interactive website, platforms to explain information related to a study and to electronically document informed assent/consent the same.

Electronic methods (e.g. digital signature) must be reviewed and approved by the EC a priori.

Process can be documented through audio or video recording (if required).

**Waiver of Consent:**

For seeking waiver of consent, the researchers should give the rationale justifying the waiver which EC can approve a waiver after careful discussion in the following situations:

1. Research cannot practically be carried out without the waiver and the waiver is scientifically justified like, cluster randomization trials.
2. Retrospective studies, where the participants are de-identified or cannot be contacted
3. Research on anonymized biological samples/data
4. Certain types of public health studies/surveillance programs/program evaluation studies
5. Research on data available in the public domain; or
6. Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent.
7. When consent of the participant/LAR/assent is not possible due to the emergency situation, informed consent can be administered at a later stage, when the situation allows for it, and if it is so envisaged, prior permission must be obtained from the EC.

**Vulnerability**

**Vulnerable Persons** are individuals/ belonging to certain groups of persons who are relatively or absolutely incapable of protecting their own interests such as:

COVID-19 patients may be additionally vulnerable of being stigmatized due to the contagious nature of the disease. Also at risk are health care workers in COVID-19 hospitals including doctors, nurses, ward staff, sanitation workers, security personnel, food suppliers, or others.

Socially, economically or politically disadvantaged individuals such as the stranded migrant workers who are susceptible to being exploited;

Incapable of making a voluntary informed decision or whose autonomy is compromised temporarily or permanently;

Able to give consent, but voluntariness/understanding compromised due to their situation;

Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent

Terminally ill patients ready to consent in search of new interventions.

**Additional Safeguards:**

Participants may be under duress and traumatized, therefore, additional safeguards are required for participants and it should be ensured that,

Research to address the needs of participants and justify inclusion of vulnerable persons.

Benefits and risks carefully determined and the risk minimization strategies are examined.

There is no coercion, force, undue influence, threat or misrepresentation or incentives.

Informed consent process is conducted in a respectful manner.

Efforts to set up support systems to deal with associated medical and social problems.

Protection of their privacy, confidentiality and rights is required at all times.

Whenever possible, ancillary care may be provided.

**Safety of Health Care Workers (HCW) involved in research:**

In wake of the pandemic, safety of researchers must get due attention as transmission of infection to one member in a lab or clinical setting could jeopardize the entire program.

Ensuring safety is the responsibility of the institution, sponsors and local authorities, since research team may be subjected to disturbing instances (trauma, humiliation and threats of violence) while conducting research.

Additional precautions such as; Prioritize research and schedules to prevent overcrowding, adequate training, appropriate biosafety precautions, expose minimum number of researchers, communication using electronic platforms, due protection gear/PPE and facilities to undertake research, safety against any assault from public or others, insurance cover etc.

**Psychological needs and mental health:**

Persons tested positive for COVID-19, their families, health workers who get in contact with COVID positive cases must be provided due psychosocial support wherever possible.

There is need to show respect, empathy and compassion and not subject them to any kind of stigma or discrimination.

Persons in isolation or quarantine may face enormous stress and anxiety. Managing the mental health and psychosocial well-being is important.

The institutions must ensure access to psychosocial and emotional support, good communication, flexible working hours, and ways to ensure physical as well as psychological well-being and mental health of those going through the crisis.