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Ethical challenges in the Covid-19 research context: a toolkit for supporting analysis and resolution

Covid-19 is compromising all aspects of society including health, political, social, economic and educational spheres. In this context, there is a premium being placed on scientific research as a source of possible solutions, with a situational imperative to carry out investigations at an accelerated rate and an additional challenge not to neglect ethical standards in a context where doing so may mean the difference between life and death. In this paper we offer a rubric for considering the ethical challenges in COVID-19 related research, in the form of an ethics toolkit for global research developed by the University of Edinburgh in collaboration with more than 200 global researchers from all over the world (Reid et al., 2019). This toolkit proposes a frame of reference for the analysis and confrontation of ethical conflicts that suggests that the conflict (and its solutions) can be found in the integrated analysis of the Place, People, Principles and Precedents, considered iteratively throughout the research journey. Two case analysis are offered to exemplify the utility of the toolkit as a flexible and dynamic tool to promote ethical research in the context of Covid-19. Keywords: Covid-19, Research, Ethics, Integrity

Introduction

Covid-19 is a new virus identified in December 2019 due to an aggressive outbreak in China (Li et al., 2020). On March 11th WHO declared the outbreak a pandemic and by the beginning of May 2020 the virus had reached five continents, leaving dramatic numbers of infections and high rates of mortality (WHO, 2020a). At a global level, international

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3 organizations and governments have promoted measures to decrease the speed of spread,
4 prevent contagion and decrease the number of deaths (United Nations, 2020) through
5 promotion of hygiene habits, the use of masks, to more extreme measures such as the
6 closure of shops and borders, and isolation or quarantine of entire populations (Brooks et
7 al., 2020; WHO, 2020b). Still, in some countries the rate of infection and the number of
8 deaths has continued pace, leading to increased global efforts to investigate the virus,
9 generate prevention and treatment strategies (Kupferschmidt. & Cohen, 2020).

19 These measures have brought a series of ethical conflicts at different levels.
20 Measures implemented by governments have involved choosing between health outcomes,
21 social outcomes and economic outcomes (McKee, & Stuckler, 2020). Frontline health
22 practitioners have faced demand that exceeds the amount of resource available in most
23 countries and required decisions such as which patients to allow into hospitals and which to
24 prioritize for the use of mechanical ventilators (British Medical Association, 2020a). At
25 each level, organizations have operated from pre-existing professional ethical guidelines or
26 emergency guidelines developed in time of previous natural disasters or emergencies
27 (British Medical Association, 2020b; Chiumento et al., 2017; UK Government, 2013,
28 2017).

42 In this document, we will focus on ethical challenges for research. Due to the global
43 crisis that Covid-19 has generated, national and international research agencies have
44 launched urgent calls to action (Frontiers, 2020; WHO, 2020c). Although there is an
45 undeniable need for research that can quickly provide useful information to deal with the
46 current phenomenon, this global humanitarian imperative brings with it an increased
47 responsibility and a series of ethical challenges not previously experienced by most
48 researchers and communities (Mormina et al., 2020). These potential ethical conflicts in the

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3 context of Covid-19 may arise, and indeed *change*, throughout the research journey (WHO,
4 2020d) and require close and iterative attention.
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8 These ethical challenges are particularly pertinent for the medical sciences. For
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10 example, the ethical challenge of generating vaccines and recruiting participants to
11 participate in clinical trials is evident. It must be considered that, in addition to the pressure
12 of the health situation, researchers face the pressure of responding to the political demands
13 of funding agencies and governments.
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19 The challenges are not just limited to the medical sciences, however. Engineering
20 sciences also face important ethical dilemmas, for example in the development of new
21 technology (e.g., mechanical ventilators) and the question of whether to support
22 development for humanitarian use or potential commercial use. Social sciences have a
23 critical role in the current situation in developing an understanding of social corollaries of
24 the pandemic and of factors that may influence uptake and adherence with preventative
25 measures such as physical distancing. Social science research can shape, for better or
26 worse, the population's understanding of the problem, adherence to preventive measures
27 and the adequate treatment of the emotional consequences of the pandemic and the social
28 measures taken to confront it (e.g., confinement) (Dalton et al., 2020).
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42 In this short document, we propose that a global research toolkit (Reid et al., 2019)
43 – developed in the context of a project at the University of Edinburgh, in collaboration with
44 more than 200 global researchers from more than 60 countries and different disciplines –
45 can be useful to assist researchers in analyzing the dynamic ethical challenges as they
46 unfold throughout this pandemic (see [https://www.ed.ac.uk/global-health/doing-ethical-
47 global-research-together](https://www.ed.ac.uk/global-health/doing-ethical-global-research-together)). This toolkit, rather than offering a rigid guide to ethical
48 regulations, offers a flexible frame of reference that has the ambition to promote ethical
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3 reflection and accountability within research teams. The toolkit proposes two fundamental
4 axes of analysis: iterative ethical analysis throughout the research journey, and ethical
5 analysis based on the 4Ps model (See figure 1).
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9 10 **Ethics throughout the research Journey**

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12 The idea of ethics throughout the research journey arises in opposition to the idea
13 that research ethics is only associated with the process of applying for project approval
14 from an ethics committee. On the contrary, ethical reflection and considerations must be
15 present during the entire research journey. Ethical accountability starts before the project
16 begins by considering the research culture of our institution and the ethics of the germinal
17 ideas of the study; it extends beyond the life of the project to the legacy that our research
18 leaves on the communities involved and on the intended (and unintended) recipients.
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28 As seen in Figure 1, at least 13 different stages are recognized in the research
29 journey and connected through an iterative process of reflection. In the current context of
30 Covid-19, the rapid execution of research processes has been prioritized encouraging the
31 normal steps of the investigation to be carried out faster than usual (Kupferschmidt, &
32 Cohen, 2020). We offer an analysis and some examples of ethical conflicts in the different
33 stages of the research journey. Our desire is not to offer an exhaustive list of all the possible
34 ethical challenges since these will depend on the context of each investigation, we simply
35 offer a framework for the analysis of real cases. We have grouped the 13 stages into three
36 sections of the research journey.
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49 ***Initial section: From research culture to ethics application***

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51 This first section looks at the beginning stages of the research included considering
52 the research culture of the organizations, the development of the research idea, the team and
53 partnership development, and the preparation of grant and ethical applications (see figure 1)
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3 In the Covid- 19 context the development of the idea, the formation of a work team,
4 the elaboration of the proposal and even the process of ethical application is hastier.
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8 Though speed is essential ethical rigor should not be relaxed since, in a context such as
9
10 Covid-19, unethical or negligent action could have serious consequences for research
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12 participants and for society in general (Mormina, et al., 2020; WHO, 2020d).
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15 While there is evidence of scientific communities from different countries coming
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17 together to establish international research teams, there are also tensions as the research
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19 space has been one of competition in a system whose traditions rewards competition and
20
21 encourages institutions and individuals to take advantage of opportunities for financial gain
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23 and career progression.
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26 Ensuring that there is a collective agreement and collective benefits from working
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28 together is essential, do researchers working in Universities that are not highly research
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30 focused feel pressure to participate because funding is desperately needed? Are the
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32 research questions have emerged from the local context or have they been superimposed on
33
34 the context?
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38 Preparing applications for grants and ethics committees also become a major
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40 challenge, both for applicants - who must plan investigations in a short time and without
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42 much evidence of health emergencies of this magnitude - as well as for review committees
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44 and ethical committees - who have a high responsibility to accept or reject projects
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46 potentially beneficial to humanity. Committees are looking for evidence of co-creation of
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48 design and of clear requests for engagement by all partners but speed may mean that these
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50 essentials are recorded as positive when in fact they are still in progress
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54 ***Middle stages: fieldwork and analysis of results***
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3 This stage includes the data collection process, the project delivery, but also the
4 process of analysis and writing of reports. There are multiple ethical challenges in the
5 recruitment process with the population and the researchers at risk of becoming ill,
6 experiencing serious side effects or directly at risk of dying (Van Griensven, 2016); as
7 such, it is essential that researchers ask, for example, how do we promote an informed
8 consent process in a population highly expectant of the potential benefits of research and
9 how do we manage the expectations of the participants and the community? How do we
10 interview in a socially responsible risk free way both for the researchers and for the
11 participants? Physical distancing an essential preventive measure of Covid-19 also poses
12 ethical challenges, particularly in relation to the reliability and validity of the data
13 collection process. This is especially salient when questionnaires or interviews are
14 conducted by telephone or internet, which requires researchers to consider whether those
15 without internet connection are being excluded from research and how this sampling bias
16 may affect the internal and external validity of the results.

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There are also some communities, such as refugee communities, whose conditions
place them at heightened risk of infection, and also creates increased vulnerability when it
comes to informed consent to participate in trials. Desperation, panic, pre-existing trauma,
mental health vulnerabilities and poor communication in a Refugee Camp setting may
make it difficult for residents to feel that they have a choice in participating in the research,
or indeed, to ascertain the difference between health services offering healthcare and
researchers trialling new treatment options. We believe all these issues should be
considered in the analysis of result and in the writing process, with particular reference to
the internal and external validity of results

Final stages: from the dissemination of results to the analysis of the legacy

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3 We strongly believe that ethical issues sometimes resulting in ethical conflicts can
4 be present even after research reports have already been written or even published. This is
5 an issue often neglected by research teams. For this reason, we propose the importance of
6 the process of analysis, dissemination, exchange of information and application to practice.
7
8 For example, if a vaccine is found soon, how will that information be handled? Will
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10 humanitarian or commercial interests be privileged for the dissemination of this
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12 knowledge? The answers to these questions will also undoubtedly be influenced by ethical
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14 conflicts that may arise from considerations of the impact and legacy of the study.
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21 No matter what are of research, scientists in all areas have a duty to transmit
22 information in a clear, accessible, quick and reliable way, sharing negative results as well
23 as positive outcomes. This challenge has been evident across different media during the
24 pandemic, with calls on the scientific community to speak up but also to speak responsibly
25 with the understanding that such reports can support positive responses but can also
26 generate panic reactions and reinforce myths and stereotypes. Many scientists are not
27 practiced at translating their research into lay-language that can be understood clearly by
28 the broader community and yet it is our ethical responsibility to do so. Open access
29 publication has also become key in sharing findings quickly with the research community
30 and submitting them to the scrutiny of peer review. Then there is the question of
31 commercialisation and the ethics of taking out patents on drugs or vaccines that may
32 prevent equitable access.
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49 PLEASE INSERT FIGURE 1 HERE
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51 **The 4Ps model**

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3 The Global Research toolkit proposes that the analysis of throughout the research
4 journey it is necessary to look at complementary aspects of the research endeavor to
5 ascertain the nature of challenges and potential solutions.
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10 The 4P's model states that ethical challenges can be helpfully analyzed by
11 considering Place, People, Principles, and Precedents. It is proposed that ethical challenges
12 are based on these 4 elements, but that solutions can also be found in them.
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17 Place. Which includes contextual aspects – cultural, political, economic, health –
18 where the research is being carried out, or where its results are relevant. For example, any
19 ethical situation related to Covid-19 will require a contextualized approach as conducting
20 research in countries where the pandemic is uncontrolled will have different requirements
21 and pose different challenges to conducting research in countries where the most acute
22 phase has already passed (or has not yet started). A solution may be effective in one
23 context, but not in another. There are also risks of ignoring key ethical issues in name of an
24 emergency or humanitarian research when in fact we should be more, not less, accountable
25 for our actions – this is a challenge perhaps familiar to global health researchers but less so
26 to the many researchers entering this global stage for the first time. During a global
27 pandemic, there are increased ethical challenges associated with working with highly
28 vulnerable populations, either because they are fighting the virus or because of fear and
29 panic associated with trying to avoid the virus may make communities and individuals less
30 able to make clear and reasoned decisions. It is important that we ask ourselves how we can
31 recruit participants in this context without taking advantage of their vulnerability?
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51 People. Which includes those involved (research team, funding sources, institutions,
52 international partners, potential participants, potential beneficiaries, etc.). The Covid-19
53 crisis requires international, interdisciplinary and inter-sector collaboration, but that
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3 collaboration brings with it differences in research power that require consideration. For
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5 example, the need to ensure the wellbeing of research participants in the context of a
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7 pandemic is an evident challenge, where the understanding of research procedures is sought
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9 without violating the principles of informed consent. Additionally, in international research,
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11 important questions include how to determine the country where the first tests of the
12
13 vaccine will be carried out without falling into neo-colonialist practices? On the other hand,
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15 when developing solutions to ethical conflicts, it is important to consider the organizations,
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17 people, regulatory entities or colleagues that could help us or advise us on how to properly
18
19 face these issues.
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24 Principles. This refers to the importance of considering, at all times, the principles
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26 and values that should guide ethical research. For example, the balance of risk-benefit is an
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28 obvious challenge to potential candidates to test a vaccine. Economic interests vs.
29
30 humanitarian interests associated with the dissemination of relevant new knowledge also
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32 come into play. We can add the difficulties of establishing procedures with scientific rigor
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34 in these contexts of urgency and limited resources.
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38 Precedent. This element refers to the need to analyze past experiences of similar
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40 ethical conflicts that can help us understand and resolve current ethical conflicts. It is
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42 especially relevant to review the current ethical regulations and the available academic
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44 material that may help us face the conflict. At the same time, researchers have the challenge
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46 of – based on their own current experience – ‘generating a precedent’ of ethical conduct in
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48 research that helps future researchers face similar ethical conflicts. This point is particularly
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50 useful to the scientific community in the future when face ethical challenges in situations
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52 similar to the current Covid-19 crisis.
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3 In the following section, we offer two examples on how to apply this analysis
4 framework in the resolution of a possible ethical conflict. The end is purely illustrative as
5 the proposed solution to the ethical conflict is will depend on the specific context in which
6 the challenge arises and the rapidly changing circumstances as the project progresses.
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10 11 12 **Case analysis 1**

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14 The case to be presented mainly covers the difficulty of establishing collaborative
15 relationships between research teams. It is clear that the complexity of the current world
16 health crisis requires collaborative, interdisciplinary, inter-university, inter-sectoral and
17 inter-cultural work. However, sometimes the personal interests of research teams or
18 universities may conflict with the scientific and humanitarian interest of having new
19 relevant knowledge to face the pandemic. As we have already outlined, this solution only
20 seeks to exemplify the reasoning behind the toolkit, we do not expect this solution to be
21 generalizable to other contexts, beyond the illustrative exercise. See table 1.
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33 PLEASE INSERT TABLE 1
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35 36 **Case analysis 2**

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38 The second case analysis addresses the ethical conflict in clinical trials where new
39 medical procedures are tested, in this case a vaccine for Covid-19. The case is located in a
40 refugee camp where there are low resources and a vulnerable population, with high risk of
41 contagion and with high expectation of receiving help. In this context, power differences
42 between researchers and potential participants can easily lead to exploitation of the
43 community. In the case, we analyze issues such as the balance between risk vs. benefit,
44 informed consent, language barriers and the following of ethical protocols and local
45 regulations. Like the previous case, the objective is merely illustrative, and we do not
46 expect this solution to be applicable in all cases. We hope that the two cases serve as
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3 examples and are useful for the reader to analyze their own ethical conflicts in their current
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5 research context. Please see table 2.
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8 PLEASE INSERT TABLE 2
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10 **Discussion**

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12 The current global situation requires the collective efforts of many different agents
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14 to face the pandemic. Doctors, nurses, and other front-line practitioners and key workers
15
16 are exerting immense effort in tackling the effects of the virus (Legido-Quigley, Mateos-
17
18 García, Campos, Gea-Sánchez, Muntaner, & McKee, 2020). This effort must be
19
20 complemented by scientists from all disciplines, collaborating with new evidence of
21
22 preventive measures and treatments to deal with Covid-19 and its associated ills, including
23
24 the impact on mental health of individuals and the longer term impacts on the social,
25
26 economic and political structure of societies (Inchausti et al., & Dimaggio, 2020;
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28 Kupferschmidt. & Cohen, 2020)
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33 We believe that scientists should respond to this call with haste and responsibility,
34
35 without neglecting compliance with ethical standards consistent with contemporary science
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37 practice and compatible with international ethical regulations.
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40 In this document, we offered a toolkit – developed collaboratively with researchers
41
42 around the world – that can help researchers analyze and search for solutions to everyday
43
44 ethical conflicts. We have briefly explained the toolkit and provided a hypothetical case
45
46 analysis. Our outline here has been brief, offering illustrations in the form of case studies to
47
48 provide the reader with general idea of the application of the model. The original source
49
50 provides more detailed information on the toolkit and its uses (Reid et al., 2019).
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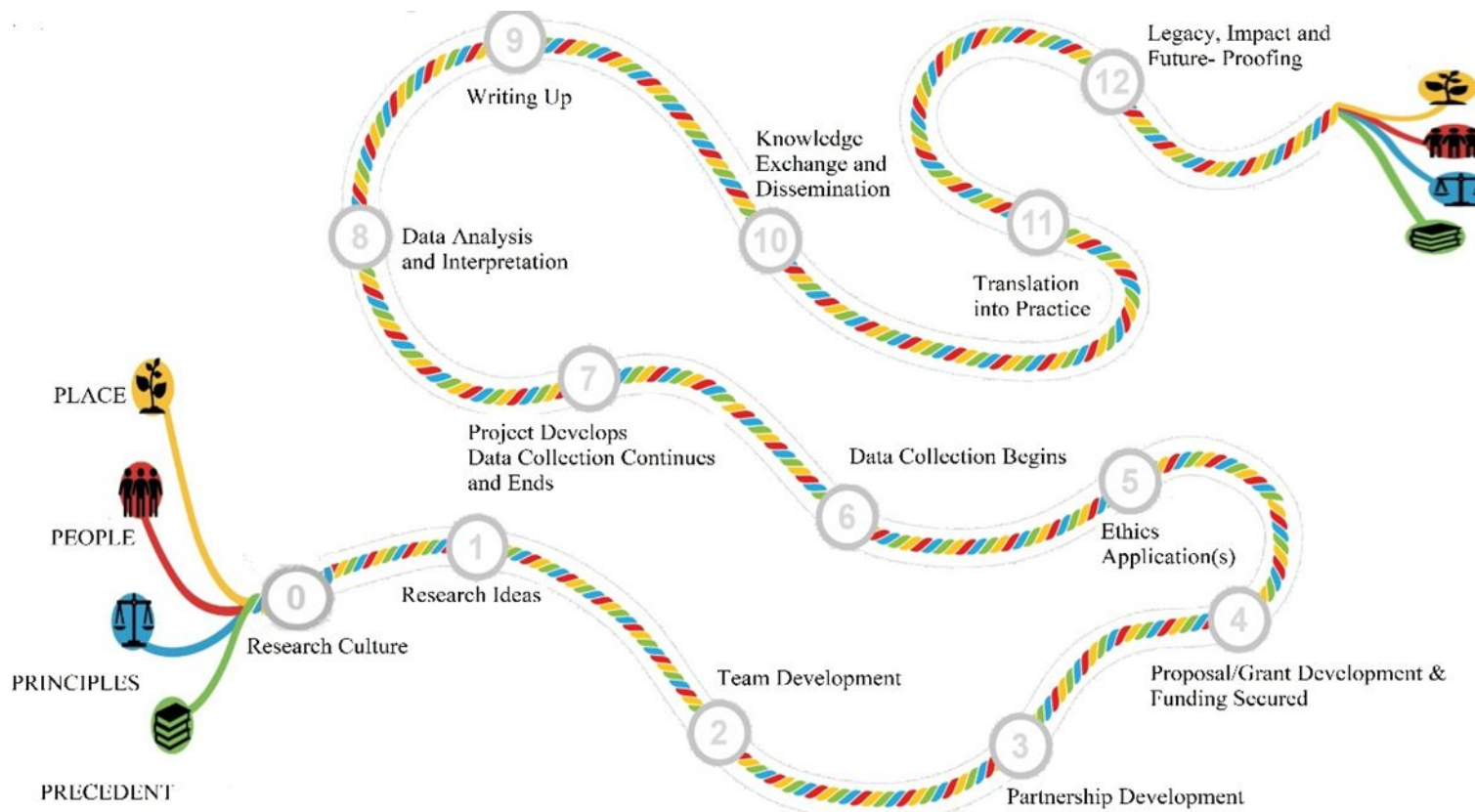


Figure 1. Fundamental axes of the toolkit

Table 1. Case analysis 1

Ethical issue	Part(s) of the research Journey?	Understanding the dilemma	Ethical Reflection	Ethical Response
<p>The research of Dr. AV and his team seeks to contribute to the development of a vaccine against Covid-19. Dr. AV knows that the research would benefit greatly if he established collaborative work with Dr. CB's team. Doctors AV and CB come from two major universities competing for leadership in the area. In recent years, their relationship has been deteriorated by conflict of interest (research funds, authorship and commercial rights). Dr. AV is unsure whether to start collaborative work with Dr. CB despite the benefits this would bring for research and, eventually, for humanity</p>	<ol style="list-style-type: none"> 0. <u>Pre-Stage</u> 1. <u>Research Idea</u> 2. <u>Team Development</u> 3. <u>Partnership Development</u> 4. <u>Proposal/Grant Development and Funding</u> 5. <u>Ethics Applications(s)</u> 6. <u>Data Collection Begins</u> 7. <u>Project Develops and Ends</u> 8. <u>Data Analysis</u> 9. <u>Writing Up</u> 10. <u>Knowledge Exchange and Dissemination</u> 11. <u>Translation into Practice</u> 12. <u>Legacy and Impact</u> 	<p>Place: Both research teams work at rival universities located in neighboring countries. The culture in both universities enhances competition more than collaboration.</p> <p>People: Dr. AV and CB work in the same area, the last 20 years have competed for the same research funds. In the last congress of their specialty they were involved in a heated public altercation</p> <p>Principles: Dr. AV's dilemma is whether to privilege his personal interests (and that of his university) or ensure the progress of research in a global health emergency.</p> <p>Precedents: What are the national and international regulations in this regard? Has this happened before? How has it been resolved?</p>	<p>Place: Both rival universities have worked together in the past. There is a cooperation agreement that offers suggestions for regulating collaboration between them.</p> <p>People: It is important to ask: who on Dr AV and Dr CB's teams or universities could help overcome this impasse? Is there someone from other universities or research teams who can help?</p> <p>Principles: Dr. AV understands the interest of humanity over personal interests are more important, but at the same time he is aware that conflicts of interest could cause the project to fail, even working together with Dr CB.</p> <p>Precedents: There are antecedents of similar situations among other investigation teams that have been mediated by a collegiate international organization.</p>	<p>Dr. AV discussed the issue with his research team. All agreed on the undeniable benefit of working with Dr. CB's team.</p> <p>One of the team members suggested also inviting Dr AS to join the project. Dr AS has worked in collaborations with both teams for the last 5 years, so could offer a technical contribution, but also act as a 'bridge' and potential mediator.</p> <p>Later, Dr. AV reviewed the collaboration agreement between the two universities which highlighted that the process for determining authorship and commercial rights of the findings was well regulated.</p> <p>In addition, Dr AV asked for a quickly advice to the international scientific society of which he and Dr CB are part of for guidance.</p> <p>As such, Dr AV invited Dr CB and Dr AS to join the project. Before commencing, they defined the limits of the relationship, signing a collaboration contract (which specified roles, functions, authorship and possible commercial rights).</p>

Table 2. Case analysis 2

Ethical issue	Part(s) of the research Journey?	Understanding the dilemma	Ethical Reflection	Ethical Response
<p>You are working in a refugee camp with 2,000 people living a context of poverty, overcrowding, weak health system, and difficulties accessing basic services. Under these conditions, the risk of transmission of Covid-19 is high. A colleague –working on a vaccine – asks you to arrange clinical trials in the refugee camp. You are unsure of the appropriateness of the request, given the level of vulnerability of the population. Your main concern is that the community may not understand the scope of the vaccine test, or the difference between a trial and a proven treatment, and may not be in a position to provide informed consent, and may have expectations that exceed reality. You do not want to exploit the community</p>	<p>0. Pre-Stage 1. <u>Research Idea</u> 2. Team Development 3. <u>Partnership Development</u> 4. <u>Proposal/Grant Development and Funding</u> 5. <u>Ethics Applications(s)</u> 6. <u>Data Collection Begins</u> 7. Project Develops and Ends 8. Data Analysis 9. Writing Up 10. Knowledge Exchange and Dissemination 11. <u>Translation into Practice</u> 12. <u>Legacy and Impact</u></p>	<p>Place: In the camp, preventive measures (hygiene and social/ physical distancing) are not possible due to overcrowding and lack of basic services – likely rates of infection will be high and services low. A successful vaccine could make a very significant humanitarian difference. Previous experience of research is low whereas access to humanitarian aid services is high – these could be confused.</p> <p>People: Refugees are anxious for help. Expectations are high, and understanding of the implications of clinical trials is low</p> <p>Principles: The importance of Covid-19 clinical trials are known, but given the associated risks, informed consent is of utmost importance.</p> <p>Precedents: Previous studies clearly show that vulnerable populations have exaggerated expectations of the benefits of clinical trials (e.g., Weinfurt et al., 2005)</p>	<p>Place: In the camp, there is a hierarchical structure with leaders validated/respected by the community</p> <p>People: Within the leaders, there are individuals with basic knowledge of medicine who are willing to explain the scope of trial to the population.</p> <p>Principles: You are aware that the community has to understand the risks vs. benefits of trial. Your intention is to explain in a clear and transparent way that is understood by the community.</p> <p>Precedents: There are protocols for conducting vaccine trials in vulnerable settings and for gaining culturally sensitive informed consent (e.g., Bonhoeffe et al., 2013). In addition, countries have their own regulations that must be reviewed before proceeding.</p>	<p>The research team meets with community leaders to explain the research, the risks, and potential benefits. The discussion is led by a member of the research team who speaks the local language. Community leaders offer to collaborate in the process of explaining the scope of the research to the community.</p> <p>Workshops are held in the community where the research risks and benefits are explained. This is conducted in the local language, supported by an explanatory video.</p> <p>After receiving clear information some participants decide to freely consent (knowing that they also have a right not to participate) and others choose not to. Those interested in taking part will participate in individual interviews to ensure they understand the risks and can provide informed consent freely. After receiving clear information some participants decide to freely consent (knowing that they also have a right not to participate)</p> <p>In addition, the recruitment process respects local protocols and is in accordance with what is required by the local authorities.</p>