



Guidance for Good Randomized Clinical Trials

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43 **Introduction**

44 **The role of randomized controlled trials in improving health**

45 Randomized controlled trials (RCTs) play a central role in generating the evidence needed to inform
 46 the development and implementation of health interventions.

47 Most interventions have modest effects on health and disease, even if they have a large effect on
 48 intermediate features (e.g. physiological or laboratory tests). However, even modest improvements
 49 in health can be important provided any benefits are not substantially offset by detrimental effects.
 50 To establish reliably whether a health intervention has any effect requires that any biases or random
 51 errors inherent in the study design are both small with respect to the expected treatment effect.

52 Unfortunately, useful evidence from good RCTs is often lacking. This can be because RCTs were
 53 never done, or those that were done failed to produce scientifically robust and clinically relevant
 54 answers, or the results were never published. This can result in failure to identify and use effective
 55 interventions or the continuing use of ineffective or hazardous interventions. Such problems waste
 56 resources, cause unnecessary harm or suffering, and reduce trust in those who develop or use
 57 health interventions. It must be made easier to do good RCTs to inform the development of better
 58 interventions and the delivery of future care.

59 **Guidance development**

60 There is a clear need for guidance to promote the unique benefits of RCTs across all contexts and
 61 which focuses on the unique strengths of randomization while setting out the underpinning
 62 principles necessary to generate reliable results safely and ethically, regardless of context. The
 63 Good Clinical Trials Collaborative (GCTC) was established to develop and promote the adoption of
 64 new guidance to address this issue. The GCTC has brought together a wide range of individuals
 65 and organizations with an interest and role to play in the design, delivery, analysis and reporting of
 66 RCTs, and in implementing the results. This includes those who fund, regulate, design, deliver, or
 67 are responsible for RCTs, those who provide quality assurance, audit or inspection functions,
 68 research organizations, ethicists, clinicians, participants, and lay health advocates. It also includes
 69 those from a wide variety of sectors (industry, academia, government, charitable, non-governmental
 70 organizations, participant and public groups) and settings (including higher and lower income
 71 countries around the world).

72 **Objective**

73 The objective of this guidance is to establish the key principles of RCTs: what makes a RCT good in
 74 its design and analysis, as well as ethical and social value; and why this is so. This guidance aims
 75 to enable those involved in RCTs (in any capacity) to work out for themselves how a RCT should be
 76 designed and delivered in a particular setting.

77 This new guidance has been developed to be:

- 78 • **Based on key scientific and ethical principles** and focused on issues that materially
 79 matter to the well-being of trial participants and the reliability of RCT results;
- 80 • **Clear, concise, consistent and proportionate** to the context and setting in which RCTs
 81 are conducted, recognizing that there are risks associated with both usual clinical practice
 82 and a lack of reliable evidence on the effects of an intervention;
- 83 • **Forward looking, fostering innovation in health interventions and trial methods**,
 84 including the appropriate use of routine healthcare data, technologies, and designs; and
- 85 • **Flexible, widely applicable, utilizable and durable** across disease areas, intervention
 86 types, development phases, trial designs, geographies and time.

87 **Scope**

88 This guidance is **intended to support all individuals and organizations involved** in the planning,
 89 conduct, analysis, oversight, interpretation and funding of **all trials in which randomization is**
 90 **used to assess the effects of any health intervention for any purpose in any setting**. The remit
 91 includes, for example:

- 92 • **Any design:** including comparisons of two or more interventions (one of which may be to
 93 provide no additional active intervention beyond usual practice); blinded or not; parallel,
 94 cluster, crossover or other design.
- 95 • **Any health intervention:** including pharmaceutical and biological therapies; medical
 96 devices; surgical procedures; vaccines; nutritional measures; cognitive, behavioural and
 97 psychological interventions; digital and public health approaches.
- 98 • **Any purpose:** intended to support reliable evaluation of the safety and efficacy of new and
 99 existing interventions; regulatory submissions; health technology assessments; and public
 100 health strategies.
- 101 • **Any setting:** including any geographic, economic or societal context; any context including
 102 RCTs based in hospital, primary care or community settings; or delivered direct to
 103 participant.
- 104 • **Any role:** including researchers and clinicians; patient and public groups (including trial
 105 participants); regulators and other government bodies; ethics committees and institutional
 106 review boards; funders; trial sponsors (e.g. academic, commercial); the health intervention
 107 industry and those who regulate or provide audit and quality assurance functions.

108 **How to use this guidance**

109 This document provides the **underpinning principles** of good RCTs. The word 'should' implies that
 110 something is generally the right approach or a good idea but absolutes are rare. The details of how
 111 the principles are applied to any particular trial will vary and the guidelines are not intended to be
 112 applied rigidly or uncritically.

113 Principles of Good Randomized Controlled Trials

114 In this guidance, 'good' should be taken to mean reliably informative, ethical and efficient. The
 115 following principles, taken together, capture the necessary qualities of a well-planned, well-run and
 116 clinically relevant trial. The methods and approaches needed to achieve these qualities will differ in
 117 small or large ways from trial to trial but their validity is universal.

118 1. Good RCTs are designed to produce scientifically sound answers to relevant 119 questions

120 RCTs should help resolve important uncertainties about the effects of health interventions.
 121 Depending on the context, the results may be needed to determine whether to proceed with
 122 development further evaluation of the intervention or inform regulatory licensing, clinical guidelines,
 123 and/or health policy. In each case, any uncertainties applying to the specific question(s) that remain
 124 at the end of the RCT should be sufficiently small to allow meaningful decisions to be made.

125 This requires the combination of:

- 126 • **Randomization without foreknowledge of intervention allocation:** so that any
 127 differences in health outcomes between the groups are either due to the effect of the study
 128 intervention or to the play of chance;
- 129 • **Adequate sample size:** to reduce the impact of *random errors* (i.e., the play of chance) on
 130 the results;
- 131 • **Unbiased assessment of outcomes:** i.e. not influenced by knowledge of intervention
 132 allocation; and
- 133 • **Intention-to-treat analyses:** to compare outcomes according to the intervention to arm to
 134 which participants were allocated and **without emphasis on data-derived subgroups.**

135 Good RCTs should include the following features:

136 **Appropriate trial population**

137 *Key Message:* The eligibility criteria should be tailored to the question the RCT sets out to answer.
 138 Inclusion criteria should not be unnecessarily restrictive. Efforts should be made to include a broad
 139 and varied population (e.g. with appropriate sex, age, ethnic and socioeconomic diversity), unless
 140 there is a good medical or scientific justification for doing otherwise.

141 Exclusion criteria should be focused on identifying individuals for whom participation would place
 142 them at undue risk by comparison with any potential benefits (e.g. based on their medical history or
 143 concomitant medication) or for whom the benefits have already been reliably demonstrated.

144 *Why this is important:* Inclusive eligibility criteria increase the relevance of the findings. They may
 145 sometimes allow assessment of whether there is good evidence of material differences in the
 146 effects (beneficial or adverse) and/or acceptability of an intervention or its delivery in any particular
 147 subgroup (e.g. based on specific genetic, demographic, or health characteristics), although
 148 statistical power to detect such differences exist may be limited.

149 **Robust intervention allocation**

150 *Key Message:* Randomization requires generation of an unpredictable allocation schedule with
 151 concealment of which intervention will be allocated to a particular participant until after the point of
 152 randomization. It should be impossible to predict in advance which individual trial participant or

153 individual cluster (e.g. hospital or city in a cluster RCT) the study intervention is likely to be allocated
154 to, so that investigators, health care providers and other staff involved, and potential participants are
155 not aware of the intervention to which they will be assigned.

156 *Why this is important:* Randomization allows for like with like comparisons so that subsequent
157 differences in health outcomes between the groups (beneficial or adverse) are due either to the play
158 of chance or are due causally to differences in the study intervention. Measures such as
159 minimization may be used to reduce the size of random differences between intervention groups,
160 provided that they are implemented in such a way that avoids potential participants and those
161 enrolling them being able to predict which intervention will be allocated at the point of
162 randomization. The absence of adequate allocation concealment prior to randomization can lead to
163 selection bias (i.e. the decision to enter a particular participant in a trial can be influenced by
164 knowledge of which intervention they are likely to be assigned to).

165 **Adequate size**

166 *Key Message:* A RCT should be sufficiently large and statistically powered to provide a robust
167 answer to the question it sets out to address.

168 *Why this is important:* For the effects of health interventions to be reliably detected or reliably
169 refuted then, in addition to randomization (to minimise biases), random errors must be small by
170 comparison with the anticipated size of the effect of the intervention. The best way to minimize the
171 impact of random errors is to study sufficiently large numbers (noting that RCTs assessing impact
172 on discrete health outcomes such as mortality will require more participants than those assessing
173 impact on continuous measures such as laboratory results as is often the case in early phase trials).

174 There are some scenarios for which it is inappropriate or challenging to randomize sufficiently large
175 numbers of participants, such as trials assessing interventions in rare diseases. For such trials, it
176 may be helpful to contribute to a broader collaboration to conduct the RCT or select a clinically
177 relevant outcome for which the effect size is expected to be larger (e.g. a physiological or imaging
178 biomarker). It may be possible to reduce the impact of random errors through the statistical
179 analyses that are done (e.g., analyses of a continuous outcome adjusted for baseline values of that
180 outcome would typically increase statistical power compared with an analysis of either mean follow-
181 up levels or an analysis of mean changes in levels) or by making assessments at a time when the
182 effects of the intervention are anticipated to be greatest.

183 **Blinding and masking of allocated trial intervention**

184 *Key Message:* Knowledge of the allocated trial intervention may influence the behaviour of
185 participants, those who care for them, or those assessing study outcomes (particularly if these are
186 subjective in nature). This can be avoided through use of placebo medications or dummy
187 interventions or by ensuring that those individuals or systems responsible for assessing participant
188 outcomes are unaware of the allocated intervention.

189 *Why this is important:* In some RCTs, knowledge of the allocated intervention can influence the
190 nature and intensity of clinical management, the reporting of symptoms, or the assessment of
191 functional status or clinical outcomes. This is particularly important for trials in which blinding of the
192 allocated intervention is not feasible or desirable. Masking (or blinding) participants, investigators,
193 health care providers, or those assessing outcomes to the assigned intervention can help prevent
194 such issues as can the use of information that is recorded separately from the clinical trial (e.g.
195 routine clinical databases and disease registries). These considerations are important for both the

196 assessment of both the efficacy and the safety of the intervention, including processes relating to
197 adjudication of outcomes and considerations of whether an individual health event is believed to
198 have been caused by the intervention.

199 **Adherence to allocated trial intervention**

200 *Key Message:* Efforts should be made to facilitate and encourage adherence to the allocated
201 intervention(s).

202 *Why this is important:* If trial participants allocated to active intervention do not receive it as planned,
203 or if those allocated to the control group (e.g. placebo or usual care) start to receive the active
204 intervention, then the contrast between the two study groups is less. Consequently, the ability to
205 assess any differences (beneficial or harmful) between interventions is reduced (and it is more likely
206 to falsely conclude that there is no meaningful difference between the interventions when in fact
207 there is one).

208 **Completeness of follow-up**

209 *Key Message:* Participant outcomes should be ascertained for the full duration of the RCT,
210 regardless of whether a trial participant continues to receive the allocated intervention or ceases to
211 do so (e.g. because of perceived or real adverse effects of the intervention). In some cases, it may
212 also be appropriate to continue follow-up for many years beyond reporting the main analyses.

213 *Why this is important:* Continued follow-up of all randomized participants (even if some stop taking
214 their assigned intervention) maintains the like-with-like comparison produced by the randomization
215 process. Premature cessation of follow-up or post-randomization exclusion of participants should
216 therefore be avoided since it may introduce systematic bias, particularly as the type of people
217 excluded from one intervention group may differ from those excluded from another. Incomplete
218 follow-up may reduce the statistical power of a RCT (i.e. the ability to distinguish any differences
219 between the interventions) and underestimate the true effects (benefits or hazards) of the
220 intervention. Extended follow-up can allow for detection of beneficial or harmful effects of the study
221 intervention that may persist or emerge months or years after the initial randomized comparison.

222 **Relevant measures of outcomes**

223 *Key Message:* The outcomes that are assessed in a RCT need to be relevant to the question being
224 addressed. These may include physiological measures, symptom scores, participant-reported
225 outcomes, functional status, clinical events, or healthcare utilization. The way in which these are
226 assessed should be sufficiently robust and interpretable (e.g. used in previous trials or validated in a
227 relevant context).

228 *Why this is important:* The ways by which the consequences of the randomized intervention are
229 measured should be sensitive to the anticipated effects of the intervention and appropriate to the
230 study question, and in general should be applicable and meaningful for the relevant population. The
231 choice of outcomes may vary depending on the extent of prior knowledge of the effects of the
232 intervention (e.g. early trials may assess the effects on imaging and laboratory markers and later
233 trials the effects on clinical outcomes). It is rarely possible or desirable to assess the full range of
234 potential outcomes in a single RCT. Instead, there should be a focus on providing a robust answer
235 to the specific, well-formulated question.

236 Proportionate, efficient and reliable capture of data

237 *Key Message:* Data collection should focus on those aspects needed to assess and interpret the
238 trial results as specified in the protocol and should not be excessive. The extent to which information
239 (e.g. on participant characteristics, concomitant treatments, clinical events, and laboratory markers)
240 is detected and recorded, and the means and level of detail to which this is done should be tailored
241 to each RCT. This should take into account what is needed to answer the trial question, the level of
242 existing knowledge about the background health condition and the intervention being studied. The
243 choice of data collection approach may also be influenced by considerations such as suitability,
244 availability, and usability as well as the extent to which such information is sufficiently accurate,
245 comprehensive, detailed, and timely.

246 Tools and methods for data collection, storage, exchange, and access should enable the RCT to be
247 conducted as designed, support privacy and security, and enable reliable and consistent analyses.
248 Digital technology and routine healthcare data can provide alternative or complementary means to
249 record information about participants and their health at study entry, during the initial intervention
250 and follow-up period, and for many years beyond, where appropriate.

251 *Why this is important:* The volume, nature, and level of detail of data collection should be balanced
252 against its potential value. Disproportionate data collection wastes time and resource. It places
253 unnecessary burden on trial participants and staff, distracts attention from those aspects of the trial
254 that have greatest consequence for the participants, and reduces the scale (number of participants,
255 duration of follow-up) of what is achievable with available resources. In some trials, it may be
256 appropriate to measure some features (e.g. intermediary biomarkers) in a subset of participants,
257 chosen on the basis of baseline characteristics or random selection, or at a limited number of
258 timepoints. The choice of method used for data collection can have an important bearing on trial
259 reliability and feasibility. Use of data standards can help ensure data quality and data integrity. Use
260 of digital technology and routine healthcare data can improve the relevance and completeness of
261 information collected (e.g. reducing loss to follow-up).

262 Ascertainment of outcomes

263 *Key Message:* Processes for ascertaining study outcomes should be the same in all randomized
264 groups. This includes the frequency and intensity of assessments. Particular care should be taken
265 to ensure that the people assessing, clarifying, and adjudicating study outcomes are not influenced
266 by knowledge of the allocated intervention (i.e. blinded or masked outcome assessment). Equally,
267 the methods for acquiring, processing, and combining sources of information (e.g. to define
268 participant characteristics or clinical outcomes) should be designed and operated without access to
269 the intervention allocation for individual participants or knowledge of the unblinded trial results.

270 *Why this is important:* If the methods used to assess, clarify or classify outcomes differ between the
271 assigned interventions, the results may be biased in one direction or other leading to inappropriate
272 conclusions about the true effect of the intervention. Therefore, the approach used to assess what
273 happens to participants should be the same regardless of the assigned intervention. Those making
274 judgements about the occurrence or nature of these outcomes should also be unaware of the
275 assigned intervention (or features, such as symptoms or laboratory assays, that would make it
276 easier to guess the assignment) for each participant.

277 **Statistical analysis**

278 *Key Message:* Trial results should be analysed in accordance with the protocol and statistical
279 analysis plan, which should be developed prior to knowledge of the study results. Any post-hoc
280 analyses should be clearly identified as such. The main analyses should follow the intention-to-treat
281 principle, meaning that outcomes should be compared according to the intervention arm to which
282 the participants were originally allocated at randomization, regardless of whether some of those
283 participants subsequently received some or none of the intended intervention, and regardless of the
284 extent to which the post randomization follow-up procedures were completed.

285 Subgroup analyses should be interpreted cautiously, especially if they are multiple in number,
286 whether pre-specified or not. In general, any prognostic features that are to be used in analyses of
287 intervention effects in RCTs should be irreversibly recorded (or sample collected) before
288 randomization.

289 *Why this is important:* The strength of a RCT is that there is a randomized control group with which
290 to compare the incidence of all health events. Consequently, it is possible to distinguish those
291 events that are causally impacted by allocation to the intervention versus those that are part of the
292 background health of the participants. Analyzing all participants according to the intervention to
293 which they were originally allocated ('intention-to-treat' analysis) is important because even in a
294 properly randomized trial, bias can be inadvertently introduced by the post-randomization removal of
295 certain individuals from analyses (such as those who are found later not to meet the eligibility
296 criteria, who are non-adherent with their allocated study treatment or who commence active
297 intervention having been allocated to a control group).

298 Additional analyses can also be reported, for example, in describing the frequency of a specific side
299 effect. It may be justifiable to record its incidence only among those who received the active
300 intervention, because randomized comparisons may not be needed to assess large effects.
301 However, in assessing moderate effects of the treatment, 'on-treatment' or 'per protocol' analyses
302 can be misleading, and 'intention-to-treat' analyses are generally more trustworthy to assess
303 whether there is any real difference between the allocated trial interventions in their effects.

304 One of the most important sources of bias in the analysis is undue concentration on just part of the
305 evidence (e.g. selective emphasis of the result in one subgroup of many or in a subgroup that is
306 defined after consideration of the data). Apparent differences between the therapeutic effects in
307 different subgroups of study participants can often be produced solely by the play of chance.
308 Subgroups therefore need to be relevant, pre-specified, and limited in number. Analysis of results in
309 sub-groups determined by characteristics observed post-randomization should be avoided because
310 if the recorded value of some feature is (or could be) affected by the trial intervention, then
311 comparisons within subgroups that are defined by that factor might be biased. It is important to
312 interpret results in specific subgroups (e.g. men vs. women) cautiously and consider whether they
313 are consistent with the overall result or not. Failure to do so can lead to people in those being
314 treated inappropriately (given an intervention that is ineffective or harmful) or untreated
315 inappropriately (not being given an intervention that would benefit them) when there is no good
316 evidence that the effect varies between them.

317 **Assessing beneficial and harmful effects of the intervention**

318 *Key Message:* Data generated during the course of conducting a RCT may reveal new information
319 about the effects of the intervention which is sufficiently clear to alter the way the trial is conducted

320 and participants are cared for, or is sufficiently compelling to change the use of the intervention both
321 within and outside the trial. Potential harms of the intervention should be considered alongside
322 potential benefits and in the wider clinical and health context.

323 *Why this is important:* Not every health event that happens in a trial is caused by one of the
324 interventions; individuals involved in a trial may suffer health events that have nothing to do with the
325 trial or the interventions being studied. (The less healthy the participants in the RCT, the more likely
326 that any health event is related to factors other than the intervention.)

327 Assessing whether signals (e.g. rates of clinical events or laboratory abnormalities) seen among
328 those allocated to receive a health intervention are significantly more or less frequent than in the
329 control group provides a reliable assessment of the impact of the intervention. It provides a fair
330 assessment of which event are causally impacted by allocation to the intervention versus those that
331 are part of the background health of the participants. In an ongoing RCT, such unblinded
332 comparisons should be conducted by a group (such as a Data Monitoring Committee) that is
333 independent (or firewalled) from the trial team to avoid prematurely unblinding the emerging results
334 to those involved in running the trial.

335 By contrast, reports of individual events that are believed (e.g. by the participant or a doctor) to be
336 caused by the intervention are much less informative due to the lack of a comparison with the
337 incidence of the event in control group and the inherently imprecise judgement of causality. The
338 exceptions are events that are rare in the types of people involved in the trial but known to be
339 potentially strongly associated with particular interventions (e.g. anaphylaxis or bone marrow failure
340 in association with drugs).

341 Harmful and beneficial effects of health interventions may have different impact or frequency, may
342 have different time courses, and may occur in particular groups of individuals. Some interventions
343 (e.g. surgery, chemotherapy) may be associated with little or even hazardous effect in the short-
344 term but provide longer-term benefit. It should also be recognised that for many interventions, the
345 benefits may not be apparent on an individual basis, such as where a detrimental outcome has
346 been prevented (e.g. a stroke or infection).

347 **Monitoring emerging information on benefits and harms**

348 *Key message:* An independent Data Monitoring Committee (DMC) provides a robust means to
349 evaluate safety and efficacy data from an ongoing RCT, including unblinded comparisons of
350 frequency of particular events, without prematurely unblinding any others involved in the design,
351 conduct, or governance of the trial. For many RCTs, particularly in earlier phase trials, the functions
352 of a DMC could be provided internally but those involved should nonetheless be adequately
353 firewalled from the trial team to ensure that awareness of results does not introduce bias (or the
354 perception of bias). Some trials may not require a DMC (e.g. if the trial is short-term and would not
355 be modified regardless of interim data).

356 *Why this is important:* All those involved in the design, conduct and oversight of an ongoing RCT
357 should remain unaware of the interim results until after the study conclusion so as not to introduce
358 bias into the results (e.g. by stopping the trial early when the results happen by chance to look
359 favourable or adverse). The requirement for, and timing and nature of, any interim analyses should
360 be carefully considered so as not to risk premature decision-making based on limited data.

361 A DMC should include members with relevant skills to understand and interpret the emerging safety
362 and efficacy data. A DMC should review analyses of the emerging data, unblinded to the
363 randomized intervention group. The DMC should advise the RCT organisers when there is clear

364 evidence to suggest a change in the protocol or procedures, including cessation of one or more
365 aspects of the trial. Such changes may be due to evidence of benefit, harm or futility (where
366 continuing the trial is unlikely to provide any meaningful new information). In making such
367 recommendations, a DMC should take account of both the unblinded analyses of the RCT and
368 information available from other sources (including publications from other trials).
369

370 **2. Good RCTs respect the rights and well-being of participants**

371 Ethical clinical trials combine seeking answers to important questions with scientific validity and
372 appropriate protection and respect for all involved, particularly participants. Independent review of
373 proposals for new research, through an Institutional Review Board (IRB), Research Ethics
374 Committee (REC) or equivalent, is an important governance tool and can help ensure appropriate
375 steps are taken to protect the rights and welfare of participants.

376 **Appropriate participant communication**

377 *Key Message:* At all stages of a RCT (before, during and after), relevant, easily understandable
378 information should be shared with trial participants, carefully balancing the duty to inform against the
379 risk of information saturation and taking account of the clinical context. Information should be
380 provided in a clear manner and in suitable languages and formats for the intended audiences.

381 *Why this is important:* Providing timely and relevant information to participants during a trial
382 facilitates ethical research with benefits to both the participants and the quality of the trial results. It
383 is essential that potential or recruited trial participants are appropriately informed but presenting
384 excessive or exhaustive detail can work against this objective by overwhelming or confusing g
385 potential participants. Care should be taken to communicate effectively and enable relevant
386 discussion. The exact approach may be influenced by the context of the research, including clinical,
387 cultural or other issues.

388 **Relevant consent**

389 *Key Message:* The trial consent process should clearly explain to potential trial participants the
390 reasons or the trial, the questions it is seeking to answer, what is involved for them, and the
391 potential benefits and risks of participation. The extent, nature and timing of information provided
392 before and during the informed consent process should be guided by the level of additional risks
393 and commitment that participation in the RCT would involve in the context of the usual clinical care
394 or circumstances that the same individuals would normally receive. The information provided should
395 prioritize the needs and expectations of the prospective participant rather than of the organization or
396 individuals conducting the RCT. Consent information should be widely accessible and readily
397 understandable, avoid legalistic or other technical language, and as succinct as possible.
398 Approaches to obtaining and maintaining ongoing consent and communication should be relevant to
399 the RCT it relates to.

400 *Why this is important:* Consent is valid if it is informed, voluntary, and competently given prior to
401 entering the trial. There are some situations in which it is not possible for an individual to give
402 informed consent (e.g. infants or individuals lacking mental capacity) or it is not practical to do so
403 because of the urgency of the medical situation (e.g. trauma or medical emergencies). Such
404 situations should not automatically preclude the conduct of RCTs (which may be the only way to
405 provide reliable information on how best to manage such health issues) but appropriate safeguards
406 should be put in place to maintain the rights of the individuals who participate. For some trials and in

407 some individual situations, explicit consent may be unnecessary. In such cases, there should be
408 minimal additional risks and burdens to participation in comparison to the usual care a prospective
409 participant might receive outside the trial.

410 **Changing consent**

411 *Key Message:* Participants should be free to stop or change the nature of their participation without
412 affecting the usual care received, and effort should be made to determine the intended meaning of
413 such individual decisions.

414 *Why this is important:* The term 'withdrawal' can mean different things to different people, ranging
415 from participants wishing to stop receiving the study intervention, to stopping attending study visits
416 in person (but perhaps be happy to be contacted or for information about their health outcomes to
417 be collected from their regular doctors or from routine health data systems), to their biological
418 samples no longer being assayed or stored, or their data no longer being processed or shared.
419 Therefore, it is clearer to avoid the term and instead clarify with the participant(s) what level of
420 participation they wish to have and what they want to cease. If this is not properly explored, and the
421 'withdrawal' is interpreted with prejudice to mean complete removal from the study, trial participants
422 may be unnecessarily and inadvertently lost to full or partial follow-up, with possible implications for
423 the reliability of trial findings, and may miss out on aspects of the RCT that matter to them (e.g.
424 attendance at study visits or being informed about the progress and results of the study).

425 **Implications of changing consent**

426 *Key Message:* The rights of an individual participant to withdraw consent for use of trial data that
427 has already been collected should be balanced with scientific and ethical requirements.

428 *Why this is important:* Removing data can result in unreliable or inconclusive findings, with ethical
429 and clinical safety consequences for both participants continuing in the trial, and the care of future
430 patients. (e.g. important safety signals may be missed.) It can be appropriate to make data which
431 has already been collected available for analysis in order to demonstrate or preserve research
432 integrity. Those involved in a trial and those whose care is influenced by its results should be able to
433 be assured that the data are valid, and that they have not been modified through inadvertent,
434 deliberate, or malicious means.

435 **Managing the safety of individual participants in the RCT**

436 *Key Message:* Detection and management of the safety of trial participants should be tailored to the
437 trial population and to what is already known about the effects of the interventions. Such
438 approaches may be modified as new information emerges (e.g. from other trials or clinical studies in
439 the relevant population). In some circumstances it may be appropriate to exclude some groups of
440 individuals from a trial if the likely risk to their health is excessive (compared with potential gain) and
441 cannot be mitigated by reasonable clinical strategies. For some blinded trials, there may be
442 occasions when knowledge of the allocated intervention for an individual participant could materially
443 influence the immediate medical management of the participant. In such circumstances, it should be
444 possible for the treatment allocation to be unblinded and disclosed to the relevant medical team
445 without delay.

446 *Why this is important:* The procedures used to detect, investigate, and respond to unwanted health
447 events for individual participants should be shaped by what is already known about the effects of the
448 intervention from previous research or usage, as well as the background epidemiological and

449 clinical features of the intended trial population (e.g. their demographics, comorbidities, and
 450 concomitant intervention). If new information emerges during the course of the trial (e.g. from other
 451 studies or as a consequence of advice provided by the trial Data Monitoring Committee) then
 452 processes and procedures for managing the safety of individual participants should be reviewed and
 453 may need to be modified (e.g. changes in the nature and timing of assessments, training provided to
 454 trial staff, information provided to participants, or in the eligibility criteria for the trial).

455 **Communication of new information relevant to the intervention**

456 *Key Message:* During an ongoing trial, new information may become available (from within the trial
 457 or from external sources) which materially changes what is known about the effects of the
 458 intervention for some or all participants. This should be communicated to those involved in
 459 overseeing, conducting or participating in the clinical trial for whom it is relevant (e.g. because it
 460 might affect their understanding of the intervention or because they are required to take some
 461 action). Such communications and reports should be informative, timely and actionable.

462 *Why this is important:* Excessive, irrelevant or uninformative reports (particularly of individual cases)
 463 distract attention from those that require action. It is often preferable to produce and circulate
 464 contextualized periodic updates that are focused on safety issues that matter. Such reports may
 465 also be provided to the Data Monitoring Committee (for consideration in the context of the unblinded
 466 emerging trial data) and to regulatory bodies (for consideration of the implications for participants in
 467 other trials and for the wider group of patients and public). The distribution of reports should be in a
 468 format and timing that is commensurate with the action that is likely to be needed and the audience
 469 for which it is intended (e.g. participants, clinicians, regulators).

470

471 **3. Good RCTs are collaborative and transparent**

472 All those involved in RCTs share responsibility for building and sustaining the trust of collaborating
 473 partner organizations and clinical communities, participants, and the wider public. Trust is
 474 undermined when RCTs are not sufficiently relevant, fair, transparent, and respectful of the rights,
 475 interests, concerns, and values of all involved (especially those people who participate in them or
 476 whose care will be influenced by the results).

477 **Working in partnership with people and communities**

478 *Key Message:* Potential participants and/or members of the relevant community provide valuable
 479 contributions to the design, execution and interpretation of RCTs.

480 *Why this is important:* The involvement of patients and relevant members of the public can play a
 481 key role in refining and prioritizing research questions; assessing RCT acceptability and feasibility;
 482 selecting of outcomes that are relevant and meaningful to the intended population; developing the
 483 RCT design and procedures; optimizing the nature and delivery of information; and encouraging
 484 dialogue about access to health interventions that prove effective. Working in partnership with
 485 people and communities is likely to increase trust and confidence, while decreasing the risk of
 486 important groups being excluded or the needs of local populations or sectors being overlooked or
 487 misunderstood.

488 **Collaboration among organizations**

489 *Key Message:* It is important that interactions between individuals in different organizations,
 490 including those in resource-rich and resource-poor settings and among commercial, academic and

491 healthcare sectors are fair and respectful of the interests, concerns and values of all involved,
 492 including trial participants and their communities. Working collaboratively with partners to consider
 493 which features of a RCT are critical to its quality, and supporting a delivery approach that is
 494 appropriate to the setting and context can enhance a trial's resilience and efficiency.

495 *Why this is important:* Collaborative working shares ideas and expertise, helps avoid misaligned
 496 approaches or substantially different priorities, and can maximise use of resources and increase
 497 efficiency.

498 **Transparency**

499 *Key Message:* Clinical trials should be registered from the outset on a publicly available trials
 500 database. Making other trial information (including the trial protocol and other trial documentation)
 501 public is strongly encouraged. Once the RCT is completed, trial reports should be publicly available
 502 in a timely manner (typically within 12 months) and should describe the study design, methods, and
 503 results in a clear and transparent manner. It can be helpful for such reports to be available in
 504 formats that permit both professional and lay readers to understand and interpret the results.
 505 Reporting results to participants and to the public requires different approaches to reporting results
 506 to the clinical and scientific community. Data sharing should be enabled at a suitable time if ethical,
 507 feasible, and scientifically appropriate.

508 *Why this is important:* Transparency and sharing of knowledge about health interventions help
 509 generate further knowledge, build and maintain trust, and give confidence both to those involved in
 510 the RCT and to those who are not. Timely communication of trial results (regardless of the findings)
 511 is vital to guide future research, reduce unnecessary duplication of effort which wastes resources,
 512 and enable care to be guided by an up-to-date evidence base. Good communication can also
 513 support wider efforts to foster potential collaborations and increase informed participation in RCTs.
 514

515 **4. Good RCTs are designed to be feasible for their context**

516 Ensuring that a trial is set up to be practicable and produce reliable, actionable results is an
 517 important scientific and ethical duty. Consideration of the context and existing resources in a
 518 proposed trial setting can better inform effective trial design.

519 **Setting and context**

520 *Key Message:* The design and implementation of RCTs should recognize and be shaped by the
 521 characteristics of the settings in which they take place. These include the health needs and
 522 preferences of communities, their ability to access to health care, and their understanding of clinical
 523 trials, as identified through appropriate involvement, consultation and engagement with patients and
 524 the public.

525 *Why this is important:* These characteristics, alongside the nature and complexity of the research,
 526 are critical in identifying the ethical issues at stake and the issues, burdens, and benefits of running
 527 the RCT in that setting. Relevant and accessible RCTs are more likely to recruit a sufficient number
 528 of trial participants. Good patient and public involvement and education across the relevant
 529 communities help shape successful recruitment and subsequent adoption of the results.

530 **Use of existing resources**

531 *Key Message:* RCTs should be tailored to be practicable given the available infrastructure in
 532 relevant settings. This includes making optimal use of pre-existing resources and facilities, including
 533 utilizing any expertise, skills, professional standards, and quality oversight mechanisms associated
 534 with routine healthcare practice. While all individuals involved in performing a RCT should be
 535 qualified by education, training or experience to perform their respective task(s), it should be
 536 recognized that there are many aspects of delivering a clinical trial that are in line with routine care
 537 and therefore may not require additional training, procedures or checks.

538 *Why this is important:* RCTs should not be wasteful of staff and participants' time, use of
 539 interventional or other medical supplies, energy, or environmental resources. Where there are
 540 strengths and safeguards in routine systems, these should not be duplicated or altered without
 541 careful justification. The closer trial processes are to routine practice for participants and staff, the
 542 more efficiently and effectively they are likely to be delivered and the fewer mistakes they are likely
 543 to make, resulting in improved quality.

544
545 **5. Good RCTs manage quality effectively and efficiently**

546 Delivery of a high-quality trial requires competent decision-making and coordinated execution. Good
 547 governance and good trial quality management can help achieve these features.

548 **Competent advice and decision-making**

549 *Key Message:* RCTs should be subject to sufficient scrutiny to support the delivery of an
 550 informative, ethical and efficient study, and to avoid, correct, or mitigate problems.

551 *Why this is important:* Effective and efficient governance (example.g. through a Trial Steering
 552 Committee) helps to maintain the scientific and ethical integrity of a trial and advise on appropriate
 553 courses of action. It should be structured to enable effective response to issues that may arise,
 554 particularly when multiple organizations are involved, and enable reasonably consistent
 555 implementation across the trial

556 Membership of trial governance structures should reflect the expertise necessary to scrutinise key
 557 roles, responsibilities, and risks, and should build on the diverse strengths and capabilities of those
 558 involved. The need for a member or component of the governance structure to have independence
 559 from trial sponsorship and management should be determined by assessing the risk that judgement
 560 and advice could be materially influenced (or perceived to be influenced) by the relationship.

561 Governance approaches should account for the opportunity cost of associated activities by
 562 considering the extent to which they might impede participants and communities from benefiting
 563 from an effective intervention or prolong the time an ineffective or hazardous intervention is used.
 564 Prolonged or excessive governance activities, which drive up unnecessary costs, deter trial designs
 565 of sufficient size or duration, or discourage clinicians and participants from being involved should be
 566 avoided.

567 **Protecting trial integrity**

568 The integrity of trial results should be protected by ensuring that decisions about trial design,
 569 delivery and analysis are not influenced by premature access to unblinded information about the
 570 emerging results.

571 **Planning for success and focusing on issues that matter**

572 *Key Message:* Good quality should be prospectively built into the design and delivery of RCTs,
 573 rather than relying on retrospectively trying to detect issues after they have occurred (when often
 574 they cannot be rectified). RCTs should be described in a well-articulated, concise, and operationally
 575 viable protocol which is tailored to be practicable given the available infrastructure in relevant
 576 settings.

577 *Why this is important:* Rather than trying to avoid all possible issues, the aim should be to identify
 578 the key issues that would have a meaningful impact on participant well-being and safety or on
 579 decision-making based on the trial results. Efforts can then be focused on minimizing, mitigating,
 580 and monitoring those issues. Such an assessment should consider the context of the RCT and what
 581 is additional or special about it by comparison with routine care. Broadly, these considerations come
 582 under four headings:

- 583 • *factors associated with the intervention* (e.g. known and potential adverse effects; comorbidities
 584 or concomitant medications that might impact safety; special requirements for administering the
 585 intervention)
- 586 • *factors associated with evaluations required to answer the study objective that would not be*
 587 *expected in usual care* (e.g. additional invasive investigations)
- 588 • *resource implications* (e.g. need for specialist imaging or laboratory assays; unfamiliar or novel
 589 procedures requiring additional training)
- 590 • *ethical and privacy implications* (e.g. access to medical records and sharing of health
 591 information with pharmaceutical companies, researchers, or regulators)

592 Such an assessment process can then be used to guide the development of error mitigation
 593 approaches such as standard operating procedures, training, and trial monitoring. Trial processes
 594 that add scientific or ethical value to RCTs should be prioritized, and those that do not, or where the
 595 additional complexity outweighs the benefit should be avoided.

596 **Monitoring, auditing and inspection of study quality**

597 *Key message:* The nature and frequency of any trial monitoring, auditing and inspection activities
 598 should be proportionate to any identified risks to study quality.

599 *Why this is important:* Good trial monitoring, auditing and inspection activities identify issues that
 600 matter (important deviations from the protocol or unanticipated issues that threaten to undermine
 601 the reliability of results or protection of participants' rights and wellbeing) and provide an opportunity
 602 to further improve quality (e.g. through modifications to the protocol and procedures, training and
 603 mentoring staff, or information provided to participants). Excessive monitoring, auditing and
 604 inspection activities and failure to focus on details that have a material impact on trial quality wastes
 605 resources, creates distraction, and demotivates staff.

606 Rational monitoring focuses on the issues that will make a material difference to the participants in
 607 the trial and the reliability of the results (e.g. trial recruitment, adherence to allocated intervention,
 608 blinding, and completeness of follow-up). It informs corrective actions, supports staff, and enables
 609 improvements. It is important not to confuse more documentation for better quality. Example
 610 approaches that may be used include central review (including statistical analysis) of trial data and
 611 performance metrics to assess performance of staff and sites, in person or virtual support and
 612 mentoring for trial staff (e.g. through observation of study visits, with participant consent), and visits
 613 to clinical trial sites and facilities.

614 Regulatory, auditing or inspection requirements should be proportionate and sensitive to the
615 scientific and ethical qualities and objectives of a RCT. They should recognise the opportunity-cost
616 of, and avoid, setting irrelevant or disproportionate requirements that might discourage the conduct
617 or participation in good RCTs that are designed to address important questions.

618

619 **Conclusion**

620 RCTs play a central role in generating the evidence needed to inform the development and
621 implantation of interventions to improve health. In promoting the unique benefits of randomization,
622 this guidance is promoting methodology that – when implemented effectively – answers questions
623 reliably.

624 Investing in and adhering to the principles of this guidance will strengthen the scientific and ethical
625 quality of any RCT. This guidance endeavours to recognize that the application of these principles
626 will look different from trial to trial. However, the essential goals remain the same and a good trial
627 will apply all the principles wisely. By supporting the key messages with explanations of their
628 importance, the guidance can act as a tool to both prompt and justify the tailored application of the
629 principles in a particular trial or setting.

630 It is important to recognize and challenge barriers to implementing the principles of this guidance.
631 Clinical trials need robust systems and administrative functions to succeed but these same systems
632 and administrative functions can fail to facilitate – or even deter – pursuit of the principles of good
633 RCTs to the detriment of individual and public health and well-being.

634 If this guidance helps the clinical trials community to develop, fund, participate in, run, regulate and
635 utilize good trials more effectively, it will have been successful. However, the authors welcome
636 recommendations for modification or refinement based on experience of use.

637 Please send commentary to contact@goodtrials.org for consideration in future work of the Good
638 Clinical Trials Collaborative.

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