

Need for Consent in Cluster Randomized Trials – A Checklist

Background. If we presume that all cluster randomized trials (CRTs) are research projects designed to yield generalizable findings, then all such trials require IRB review and approval. The need for written informed consent from trial participants, though, will vary as a function of trial characteristics, level of risk to participants, and feasibility of obtaining consent. Local IRBs may interpret consent regulations differently and have differing views of the need for specific types of consent, but the checklist is designed to serve as a guide for investigators in determining the type of consent likely to be required for different types of CRTs.

The checklist is designed for a prototype trial in which a “cluster” of clinicians (e.g., a primary care clinic) is the unit of randomization, and that each cluster includes both clinicians and patients. The same general principles could be applied to other types of CRTs that involve other types of staff/employee participants (e.g., administrators) or other types of individual participants (e.g., health plan members, community residents).

Does the study require written informed consent from individual clinicians?

1. Do the study procedures involve any risk of physical harm to clinician participants (e.g., administration of a toxic substance with which clinicians are not generally familiar, or use of a device or tool with which clinicians are not generally familiar)? Y/N
2. Do the study procedures involve any risk of emotional harm to clinician participants (e.g., discussion of emotionally sensitive topics with patients)? Y/N
3. Do the study procedures involve any risk of harm to professional reputation or referral relationships for clinician participants (e.g., public reporting of quality performance or patient satisfaction data)? Y/N
4. Do the study procedures involve any risk of professional liability actions or other forms of complaints by patients of clinician participants (e.g., study requires physicians to prescribe drugs or to use automated decision aids that are not “standard of care” in local community)? Y/N
5. Do the study procedures involve a potential risk of privacy or confidentiality of information about clinician participants (e.g., review of medical records not otherwise subject to review, or public disclosure of care patterns or quality data)? Y/N

{A “yes” answer to any of the above questions suggests that a non-trivial level of risk for individual clinician participants in the CRT exists, and that written informed consent from those participants may be required. Continue to questions 6-10. A “no” answer to all of the above questions suggests that the level of risk is low enough to justify a waiver of consent requirements from the IRB. }

6. In order to have a valid test of the study hypothesis, is it essential that individual clinician participants be unaware of details of the study design (e.g., characteristics of study arms to which they have not been assigned) or unaware that a study is being conducted at all? Y/N

7. Is it impossible in practice, given operational details of the study protocol, to seek and/or obtain written informed consent from individual clinician participants? Y/N

8. Will the process of obtaining written consent itself create a bias that would jeopardize the validity of study findings (e.g., physicians become more self-conscious about prescribing patterns in the context of a study and make different decisions than would be the case otherwise)? Y/N

{A “yes” answer to any of questions 6-8 suggests that the investigator may petition the IRB for permission to conduct the study without a requirement for written informed consent, but that the burden of proof will be on the investigator to show that the benefits of the study outweigh any potential risks and that the study cannot be done with a consent process included.}

9. Have the potential participating clinicians signed an agreement in advance to participate in formal studies of the type being proposed? Y/N

10. As a condition of employment or membership in a group (e.g., a group practice), have individual clinicians agreed to participate in studies of the type being proposed if a legitimate representative of the group has agreed to participate on behalf of the group? Y/N

{A “yes” answer to questions 9 or 10 suggests that the study may go forward without explicit written consent from individual clinician participants, as long as the study falls within the boundaries of types of studies for which “advance consent” has been obtained, or there is formal consent obtained from a legitimate representative of the group.}

Does the study require written informed consent from individual patients?

1. Do the study procedures involve any risk of physical harm to individual patients (e.g., adverse reactions to medications, complications of tests or procedures)? Y/N

2. Do the study procedures involve any risk of emotional harm to individual patients (e.g., discussion of emotionally sensitive topics)? Y/N

3. Do the study procedures involve a potential risk of privacy or confidentiality of information about individual patients (e.g., disclosure of medical or behavioral information not otherwise available)? Y/N

4. Do the study procedures involve a significant time or effort or monetary cost to patients that would not otherwise be present (e.g., time to participate in health education sessions)?

{A “yes” answer to any of the above questions suggests that a non-trivial level of risk for individual participants in the CRT exists, and that written informed consent from those participants may be required. Continue to questions 5-9. A “no” answer to all of the above questions suggests that the level of risk is low enough to justify a waiver of consent requirements from the IRB.}

5. In order to have a valid test of the study hypothesis, is it essential that individual patient participants be unaware of details of the study design (e.g., characteristics of study arms to which they have not been assigned) or unaware that a study is being conducted at all? Y/N

6. Is it impossible in practice, given operational details of the study protocol, to seek and/or obtain written informed consent from individual patient participants? Y/N

7. Will the process of obtaining written consent itself create a bias that would jeopardize the validity of study findings (e.g., patients become self-conscious about medication adherence patterns and change those patterns as a result)? Y/N

{A “yes” answer to any of questions 5-7 suggests that the investigator may petition the IRB for permission to conduct the study without a requirement for written informed consent from patients, but that the burden of proof will be on the investigator to show that the benefits of the study outweigh any potential risks and that the study cannot be done with a consent process included.}

8. As a condition of being a patient in a particular setting, or being a member of a health plan, have potential individual participants signed an agreement to participate in research projects of the type being proposed? Y/N

9. As a condition of being a patient in a particular setting, or being a member of a health plan, have potential individual participants signed an agreement to participate in research projects of the type being proposed if a designated representative agrees on their behalf? Y/N

{A “yes” answer to questions 8 or 9 suggests that the study may go forward without explicit written consent from individual patient or plan member participants, as long as the study falls within the boundaries of types of studies for which “advance consent” has been obtained, or there is formal consent obtained from a legitimate representative of the group.}