



Sample Text That Can Be Used to Justify Appointing an LAR

What is the purpose of this document?

Below we provide sample text that you can use in IRB applications or with Sponsors to provide the rationale for, and help justify, asking participants to appoint a Legally Authorized Representative (LAR). We have included key references from the literature supporting this practice.

How can I use the text you provide?

You can use the text to support IRB applications or to justify to Sponsors the rationale for asking participants to appoint an LAR. For instance, you could use the text below in the “Background”, “Rationale”, or “Protocol” sections of the IRB application. IRB applications may ask for relevant references, which we have also provided. This information can also be used for Sponsors to justify the rationale for asking participants to appoint an LAR, or other individuals who require further information on this practice.

**You have permission to use the text below verbatim,
or to adapt it as needed for your purposes.**

Suggested text and references to support asking participants to appoint an LAR

General text to justify the use of LARs, including when no state laws exist:

The revised (2018) federal regulations for the protection of human subjects (45 CFR 46) define a Legally Authorized Representative (LAR) as someone “who is authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation.”¹

The Office of Human Research Protections (OHRP) guidance states that anyone who can serve as a proxy or surrogate decision maker for healthcare decisions could serve as an LAR for research participation decisions.² While most states lack LAR specific laws, OHRP advises that “in these states law that addresses who is authorized to give consent on behalf of another person to specific medical procedures or generally to medical treatment may be relevant if the research involves those medical procedures or medical treatment.”³

Evidence indicates that a majority of older adults and adults with Alzheimer’s disease support the idea of letting an LAR make research decisions on their behalf.^{3,4}

Rationale for use of LARs if participants lack capacity to provide informed consent:

When participants lose the ability to consent to a complex research study, they often retain the ability to appoint an LAR because this is a much simpler cognitive task.⁵ Consenting to a complex research study requires learning and retaining a lot of new and technical information. The decision to appoint an LAR involves trusting someone else to make a decision. This choice is often based on existing close relationships.

Rationale for use of LARs with research participants who do not lack capacity to provide informed consent, such as longitudinal studies:

Participants may understand consent information upon enrollment, but lose understanding

of a protocol later, threatening the validity of ongoing consent.⁴ The National Institutes of Health (NIH) recommends asking participants to appoint an LAR at the outset of a study if consent capacity is, or might, diminish during the course of a study.⁵

References

1. Federal Policy for the Protection of Human Subjects (45 CFR 46). In: United States Office of the Federal Registrar, ed2018.
2. Office for Human Research Protections. Informed Consent FAQs. U.S. Department of Health and Human Services. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html>. Accessed2020.
3. Kim SYH, Kim HM, McCallum C, Tariot PN. What do people at risk for Alzheimer disease think about surrogate consent for research? *Neurology*. 2005;65(9):1395-1401.
4. Kim SY, Kim HM, Langa KM, Karlawish JH, Knopman DS, Appelbaum PS. Surrogate Consent for Dementia Research: A National Survey of Older Americans. *Neurology*. 2009;72(2):149-155.
5. Kim SY, Karlawish JH, Kim HM, Wall IF, Bozoki AC, Appelbaum PS. Preservation of the capacity to appoint a proxy decision maker: implications for dementia research. *Archives of General Psychiatry*. 2011;68(2):214-220.