NIA IMPACT COLLABORATORY
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2021-2022 Lived Experience Panel

Ethical Challenges in Conducting Research Using a Waiver of Informed Consent with People Living with Dementia

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Executive Summary

This report shares the results of two meetings with the Lived Experience Panel. In these meetings, members of the IMPACT Ethics and Regulation Core discussed research ethics with the Lived Experience Panel.

The meetings began with a presentation about protecting people who participate in research studies. Members of the IMPACT Ethics and Regulation Core discussed **waivers of informed consent**. **Informed consent** is the process of sharing information about a study, including all the potential good and bad things that could happen to someone in the study, and then asking a person if they agree to be part of the study. A **waiver of informed consent** means the informed consent process is not required because the study has little risk and other protections are in place. The Ethics and Regulation Core members shared an example study to help explain the idea of informed consent and waivers of informed consent. They asked panel members how they would feel if the long-term care residence they or a loved one lived in participated in a trial like the example.

Key Takeaways:

- Panel members believe that participating in research is important for answering questions that can improve the lives of people living with dementia and their care partners. However, bad things can happen during research, and it can be disruptive to the lives of people living with dementia.
- While some panel members felt that a waiver of informed consent was never appropriate, others felt that a waiver could be appropriate if the researchers talked with people living with dementia, their care partners, and other stakeholders (e.g., paid caregivers) in advance to better understand how the people in the study might feel.
- Lived Experience Panel members were especially concerned about risks that could disrupt or harm quality of life, increase symptoms, or increase dependence on others.
- Researchers should use research procedures that are “dementia-friendly”. They should design studies with input from people living with dementia, their care partners, and other stakeholders.
- Researchers should share information about the study with people living with dementia, their family members and care partners, and other stakeholders in ways that are respectful and easy to understand.
- Members of the Lived Experience Panel would like to share these takeaways with as many researchers as possible. They would like researchers to use these ideas when creating new studies. To that end, the Ethics and Regulation Core is committed to: incorporating this feedback to inform consultations, encouraging investigators to incorporate these takeaways into the design and conduct of their research, and sharing this summary widely.

About NIA IMPACT

The National Institute on Aging (NIA) Imbedded Pragmatic AD/ADRD Clinical Trials (IMPACT) Collaboratory (U54AG063546) was established in 2019 to build the nation's capacity to conduct embedded pragmatic clinical trials (ePCTs) of non-pharmacologic interventions within health care systems to improve the care of people living with Alzheimer's disease and Alzheimer's disease Related Dementias (AD/ADRD). The IMPACT Collaboratory does this through a coordinated effort between IMPACT's leadership and topic-focused Cores and Teams to:

- Develop and disseminate best practice research methods
- Support the design and conduct of embedded pragmatic clinical trials (ePCTs), including pilot studies
- Build investigator capacity through training and knowledge generation
- Catalyze collaboration among stakeholders, healthcare providers, and investigators
- Ensure research includes culturally-tailored interventions and people from diverse and under-represented backgrounds

Ten topic-specific Cores and Teams work with the Administrative Core and funded investigators to accomplish the mission of the IMPACT Collaboratory. These Cores and Teams are comprised of experts in their fields who work together under the direction of IMPACT leadership to develop and share best practice research methods, support the design and conduct of ePCTs, and provide guidance to IMPACT members and investigators.

About the Alzheimer's Association

The Alzheimer's Association is the leading voluntary health organization in Alzheimer's care, support, and research. Its mission is to lead the way to end Alzheimer's and all other dementias by accelerating global research, driving risk reduction and early detection, and maximizing quality care and support. The Alzheimer's Association vision is a world without Alzheimer's and all other dementia.

About the Lived Experience Panel

The Lived Experience Panel (LEP) reflects a coordinated effort between the National Institute on Aging IMPACT Collaboratory and the Alzheimer's Association. The Lived Experience Panel is a group of nine to twelve people living with dementia or caring for people living with dementia who help inform research priorities and challenges by sharing their thoughts and experiences with researchers from IMPACT's Cores and Teams in periodic panel meetings. The panel meets at least four times a year, covering different topics that may span more than one meeting. Generally, each topic area is introduced with a presentation by IMPACT research team members, followed by a discussion with panel members to capture their thoughts and feedback on the topic presented.

The diverse members participate in panel activities for one or more years. New panel members are added as previous panel members complete their participation period.

Lived Experience Panel members were identified through an outreach and application review process, and first convened in Spring 2021. The panel that participated in generating this report was composed of eleven people reflecting various perspectives, including:

- Four people with a documented diagnosis of early-stage Alzheimer's, Mild Cognitive Impairment (MCI) or other early-stage dementia
- Four care partners representing the perspective of one or more individuals who are living with middle- or late-stage dementia or who are deceased
- Three care partners representing their own experience caring for a person living with dementia

The types of dementia represented by panel members were: Alzheimer's (6), Vascular dementia (2), Dementia (not otherwise specified) (1), Lewy Body dementia (1), Parkinson's disease (1), Frontotemporal dementia (2), Mild Cognitive Impairment (1). Some participants represented more than one type of dementia. The Panel included people with the following characteristics and identities: Female (9), Male (2), Asian-American (1), Black or African-American (3), White (7), Latina (2), and LGBTQ+ (2).

The Lived Experience Panel Report

Summary reports are written by the IMPACT core or team that facilitates the meeting/s for each topic area and reviewed by members of the Lived Experience Panel before being published and shared with the public. All reports are available on the IMPACT website.

Acknowledgements

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Introduction to this Report

This report documents the insights gained in two meetings with the Lived Experience Panel, featuring conversations related to ethical challenges in conducting embedded pragmatic clinical trials among people living with dementia and their care partners using waivers of informed consent.

The Ethics and Regulation Core held meetings with the Lived Experience Panel over Zoom on December 14, 2021 and January 4, 2022. Discussions were led by Jason Karlawish, MD, Emily Largent, PhD, JD, RN, and Steve Joffe, MD, MPH, and Core members Alex John London, PhD and Julie Lima, PhD, MPH were present. The meetings included a presentation of background information about research protections, waivers of informed consent, and a presentation of an example research study which involved using a waiver of informed consent. After the presentations, the panel members were asked to discuss five questions, including:

- How would Lived Experience Panel members feel about a long-term care residence that they or their relative live in participating in the hypothetical research study?
- How would Lived Experience Panel members feel about the example research study being conducted with a **waiver of informed consent**?
- What do Lived Experience Panel members think is "minimal risk" in the lives of people living with dementia and their care partners?
- How can researchers "protect the rights and welfare" of people living with dementia and their care partners when they conduct studies using waivers of informed consent?
- How should researchers notify people with dementia and their care partners about research being conducted with a waiver of informed consent?

The Ethics and Regulation Core met with the Lived Experience Panel over Zoom on April 27, 2022 to review and provide feedback on a draft of this report, which had been provided to members in advance of the meeting. This final report has been updated to reflect that feedback.

Background on Research Protections and Waivers of Informed Consent

The purpose of the introductory discussion was to provide panel members with background information related to human subjects protections. Meeting leaders from the Ethics and Regulation Core discussed two key protections for research participants: independent review by an Institutional Review Board (IRB) and informed consent.

An **Institutional Review Board (IRB)** is a group of experts who are not connected with the research study. In order to protect participants, these experts independently review and approve a study before any participants are enrolled. They assess whether the study is scientifically and ethically sound and meets regulatory requirements.

Informed Consent is a process in which participants or their legally authorized representatives are given important information, including possible risks and benefits, related to participating in a research study.

The practice of requiring researchers to obtain informed consent from research participants is grounded in the research ethics principle of **respect for persons**. Based on this principle, potential participants are not obligated to agree to be part of research. Instead, potential participants should have the opportunity to decide for themselves whether or not they want to participate in a particular study. This decision usually occurs through an ongoing process of informed consent. In the **informed consent process**, potential research participants are given key information about a study. Key information includes: the purpose of the study; tests or procedures that are part of the study; risks and potential benefits of participating; how long the study will take; and whom to contact with questions or concerns. Potential research participants are then asked if they agree to participate. Those who agree to participate generally give verbal consent and sign an informed consent document.

Waivers of informed consent are permissible under the Federal Policy for the Protection of Human Subjects or **"Common Rule"** when a study meets certain conditions as determined by an Institutional Review Board. The Institutional Review Board must review the study and decide that: the research poses no more than minimal risk to participants; the research could not practicably be carried out without a waiver; the waiver or alteration does not violate the rights and welfare of participants; and participants will be notified, if appropriate, that they were part of research. When an Institutional Review Board grants a **waiver of informed consent,** the research team does not have to follow the informed consent process described above. The research team does not have to share key information about the study or ask individuals if they agree to participate in the study.

In recent years, research ethicists have explored the perspectives of diverse stakeholders, particularly patients and members of the public, about approaches to informed consent for pragmatic research, such as that supported by the IMPACT Collaboratory. There is a gap in this literature, however, which doesn't include the views of people living with dementia and their care partners.

- We explained that some studies, including some of the embedded pragmatic clinical trials with people living with dementia and their care partners supported by the IMPACT Collaboratory, are conducted with waivers of informed consent.
- We walked through an example research study that would be expected to qualify for a waiver of informed consent. The example presented was of a study in which the research team wanted to see if mailing a brochure about the benefits of meditation for people living with dementia would increase the number of people reporting that they participated in meditation at their next primary care visit (Figure 1). We discussed the appropriateness of a waiver of informed consent for this study by walking through each of the regulatory conditions for a waiver and discussing why they were met.

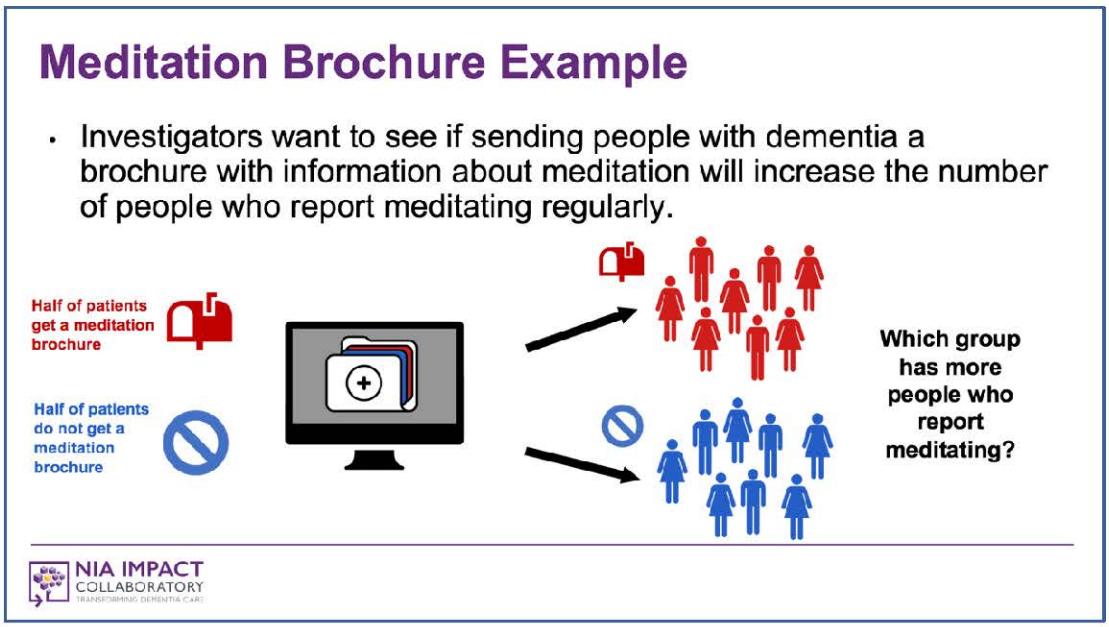

Figure 1. Example of a trial that might be conducted utilizing a waiver of informed consent.

Presentation of Example: Nursing Assistant Shift-Length Study

To illustrate the ideas being discussed and to motivate a discussion of some of the ethical issues related to conducting embedded pragmatic clinical trials among people living with dementia and their care partners, the group used an example of a study about changing the length of nursing assistant shifts within participating long-term care residences. We recognize that the presentation of an example case is useful for illustrating concepts and motivating discussion; however, the presentation of an example case can ground the discussion in the specifics of that case and people might want information that is not available in the example.

Members of the Ethics and Regulation Core presented an example in which a researcher was seeking to understand whether 8-hour or 12-hour shifts for nursing assistants resulted in better outcomes, which were defined as reduced hospitalizations among people living in long-term care residences (Figure 2). We selected hospitalization as the outcome because members of the Lived Experience Panel previously identified hospitalization as an important outcome to people living with dementia and to their care partners.

We began by discussing one possible approach to answering the researcher's question.

Initial Plan: The long-term care residences in the sample that normally use 8-hour shifts for nursing assistants would be *allowed to choose* whether they would keep 8-hour shifts for nursing assistants or whether they would change to 12-hour shifts for nursing assistants.

As discussed with the members of the Lived Experience Panel, a shortcoming of this initial plan was that, because long-term care residences were allowed to choose the shift length they preferred, it was possible that those facilities that kept 8-hour shifts were meaningfully different than those that adopted 12-hour shifts—that is, there might be selection bias. **Selection bias** occurs when there are important differences between the groups taking part in a study. If there are important differences, the results of the study may not be valid. That is, the researcher could not be certain whether any difference in hospitalizations was due to shift length or due to some other factor.

We proposed a revised research plan that could address the problem of selection bias; this was an embedded pragmatic clinical trial.

Revised Research Plan: In the revised research design, half of the long-term care residences in the sample would be randomized or *randomly assigned* to either keep 8-hour shifts for nursing assistants or to switch from 8-hour to 12-hour shifts for nursing assistants.

Randomization means that participating long-term care residences would be assigned by chance to either 8-hour or 12-hour shifts for nursing assistants. Neither the researcher nor the long-term care residence would get to choose the shift length. This helps to address the problem of selection bias that came up in the initial plan by making sure the two groups of long-term care residences are similar to one another. By doing this, the researcher can be more confident that any difference in hospitalizations between the facilities with 8-hour shifts for nursing assistants and those with 12-hour shifts for nursing assistants is due to shift length rather than another factor.

Figure 2. Example study of shift length on patient outcomes.

We explained to the panel that, because randomization was happening among long-term care facilities, rather than among individuals living within the facilities, it would be difficult, if not impossible, to get informed consent from individual residents or their legally authorized representative(s). Thus, the study would likely need to be conducted with a waiver of informed consent or it could not be conducted at all.

We also explained to the panel that owners and managers of long-term care facilities can typically change nursing assistant shift length without conducting research and without obtaining consent from residents and family members. When such changes are made outside of research, it is difficult to learn about the effects of such changes on residents' wellbeing.

The hypothetical trial of shift length was designed such that members of the Lived Experience Panel could reasonably disagree about whether or not a waiver of informed consent would be appropriate. The example was meant to show panel members the challenging ethical and regulatory questions that researchers, Institutional Review Boards, and the IMPACT Collaboratory members wrestle with as they design and conduct embedded pragmatic trials for people living with dementia and their care partners.

Following the presentation of the hypothetical study, members of the Lived Experience Panel were asked to discuss five related questions.

Topic 1: How would Lived Experience Panel members feel about the long-term care residence that they or their relative live in participating in the example study about effects of nursing assistant shift-length?

Members of the Lived Experience Panel were asked to think about how they would feel or what they would think if they or their loved one was a participant in the example study seeking to understand whether 8-hour or 12-hour shifts for nursing assistants resulted in reduced hospitalizations for residents of a long-term care residence.

The Ethics and Regulation Core asked several questions to prompt discussion: What do you think are the good things—the upsides or the benefits—of this study? What do you think are the bad things—the downsides or the risks—of this study?

Responses from Panel members about the example study and research in general

Lived Experience Panel members shared a range of responses that reflected positive and negative feelings about the nursing assistant shift-length study specifically and research participation broadly:

Positive reflections from Panel members:

- Participating in research makes you feel like a "helper." Some members noted that they or their family members like to feel that they are helping others.
- Research participation is important for answering questions that can improve the lives of people living with dementia and their care partners.
- The outcomes studied in research, such as hospitalization rates, are important to people living with dementia and to their care partners, and we won't know what works to improve these outcomes without research.
- Research can mean "more eyes" on patient care, for example, if research staff are in the clinic or long-term care residence.
- Research is a valuable opportunity to get the perspectives of people living with dementia as well as the perspectives of their care partners and families.

Negative reflections from Panel members:

- Research can be disruptive to valued routines and relationships for people living with dementia. For example, some long-term care residents have favored nursing assistants with whom they prefer to interact or from whom they prefer to get assistance with activities of daily living. Changes in staffing that would impact time and care from preferred care providers would be unwelcomed and disruptive.
- The risks and benefits of research are uncertain.
- Research may pose risks and burdens to others who are affected by a study. For example, in the example study, nursing assistants will be affected by changes in their shift length. Members of the Lived Experience Panel noted that changes in shift length may affect the nursing assistants' home lives or limit their ability to work a second job or take on additional shifts for more income.
- Research might strain an already short-staffed and stressed environment.
- Lived Experience Panel members noted that not all people living with dementia are aware of opportunities to participate in research or the importance of research. Members identified the importance of educating people living with dementia and their care partners about research. For example, it may be helpful to educate people living with dementia and their care partners about research at the time of a dementia diagnosis.
- Even within the population of people living with dementia and their care partners, individuals may hold differing views about research. For instance, past experiences in

the health care system may lead some people to be more or less enthusiastic about research participation. Two populations merit particular mention:

- Lived Experience Panel members noted that health care systems and personnel are not always "dementia-friendly". Past difficulties navigating the health care system, negative past experiences participating in research, or past experiences of stigma and discrimination in the context of care or research may limit individuals' desire to participate in research going forward. As one member said, *"First impressions are lasting ones."*

- Lived Experience Panel members emphasized that some individuals may have encountered discrimination or experienced racism in the health care system. While members recognized the importance of diversity and inclusivity in research, they noted that these personal experiences, coupled with knowledge of historical research abuses, may limit the desire of racial and ethnic minorities to participate in research.

Topic 2: How would Lived Experience Panel members feel about the example nursing assistant shift-length study being conducted with a waiver of informed consent?

After Topic 1, Lived Experience Panel members were asked to reflect on what had been discussed. In light of the good things and bad things about the example study, how would panel members feel about the study of shift length being conducted with a waiver of informed consent?

Responses and recommendations from Panel members about conducting the study with a waiver of informed consent

Lived Experience Panel members shared their thoughts about being involved in research where a waiver of informed consent was used:

- Researchers—and the research enterprise—should be trustworthy. Trustworthiness is a minimum requirement.

- Not all panelists favored waivers of informed consent. Several Lived Experience Panel members expressed a belief that there should *"always be consent."* These members were concerned that waivers of informed consent could lead to unfairness.

- Even if a waiver of consent is granted by an Institutional Review Board, research shouldn't be kept secret. It is essential to have transparency. One member noted, *"No secrets, no surprises!"*

- Researchers should consult with residents and families before introducing an intervention or program that will affect the care or environment of a person living with dementia, even if they were granted a waiver of informed consent. The importance of consultation was repeatedly emphasized by members of the Lived Experience Panel.

One used the familiar expression *"nothing about us without us!"* to underscore the importance of consultation.

    - Without consultation with residents and their families, researchers may not be able to appreciate the ways in which even subtle changes to staffing or to daily routines might adversely impact the lives of people living with dementia. For example, changes in scheduling might disrupt valued relationships with a nursing assistant or with other residents; or, disruption of a familiar routine might result in anxiety.

- In addition to seeking buy-in from people living with dementia and their families or care partners, it is important to cultivate buy-in from other relevant stakeholders, such as long-term care residence staff, when a waiver of consent is used. Some members indicated that they would feel more comfortable participating in research if the residence staff had been consulted about the study and were supportive of it.

Topic 3: What is minimal risk in the lives of people living with dementia and their care partners?

One of the conditions for securing a waiver of informed consent is that the study is no more than minimal risk. According to the Common Rule, "**Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

We discussed that the definition of minimal risk is subject to interpretation and that people can reasonably disagree about what it means for research to be minimal risk. One challenge in deciding whether a research intervention is minimal risk is specifying whose daily life we are thinking about. We asked the members of the Lived Experience Panel to think about what they think of as minimal risk for themselves or their family members.

Responses and recommendations from Panel members about minimal risk for people living with dementia

In response to questions about minimal risk, Lived Experience Panel members shared the following thoughts:

- What counts as "minimal risk" can vary across time and situations.

- Individuals will have different ideas about what is minimal risk for them. For example, some members of the Lived Experience Panel noted that the outcome of interest in the nursing assistant shift-length study example was hospitalization. While they agreed that this was an important outcome to people living with dementia and their care partners, they felt that, if the study increased risk of hospitalization, they would consider this to be greater than minimal risk because hospitalization is not a small or minimal issue for them.

- The likelihood or probability of an adverse outcome should be considered, not just its severity or magnitude.
- The risks of daily life for people living with dementia and their care partners have changed due to COVID-19, given the risks of serious illness, hospitalization, and death.
- Lived Experience Panel members are especially concerned about risks that could be disruptive to or negatively affect quality of life, increase symptoms, or increase dependence on others.

Topic 4: How can researchers "protect the rights and welfare" of people living with dementia and their care partners when conducting studies that use waivers of informed consent?

Another condition for securing a waiver of informed consent is that conducting the study will not negatively affect the rights or welfare of participants. We discussed the idea that, much like minimal risk, the concept of "rights and welfare" is subject to interpretation. The Ethics and Regulation Core members asked panel members to share their thoughts about this and describe how they understood rights and welfare. They then asked the panel how researchers might protect and promote the rights and welfare of people living with dementia and their care partners.

Responses and recommendations from panel members about protecting the rights and welfare of people living with dementia and their care partners

In response to the conversation about research participant rights and welfare, Lived Experience Panel members shared the following suggestions:

- Researchers should be committed to implementing the results of the research once the study is completed.
- The rights and welfare of people living with dementia and their care partners should be considered, but the rights and welfare of other stakeholders that are also likely to be impacted by research efforts, such as family members and long-term care residence staff, should also be considered.
- Individuals affected by the research should be consulted about research. For example, researchers should engage with a group like the Lived Experience Panel when designing a study to better understand the views of people living with dementia and their care partners.
- Researchers should ensure that their research procedures and facilities are "dementia friendly." For example, if a research participant needs an MRI, make sure that someone from the study staff is available to escort that participant back to the waiting area where they can rejoin their care partner or allow the care partner to accompany the person living with dementia for research procedures.

- Researchers should consider the potential impact of research procedures on valued relationships (e.g., between residents in a long-term care residence or between residents and staff members) when designing a study.
- Researchers should seek to understand the interests of the communities where the research is occurring and the cultural values of the prospective participants.
- Researchers should consider the needs and interests of individuals who have no family or friends involved in their care.
- Participants should be notified about the research, if possible (see below).

Topic 5: How should researchers notify people living with dementia and their care partners about research being conducted with a waiver of informed consent?

If research is conducted with a waiver of informed consent, researchers are required, whenever appropriate, to provide participants with additional related information after their participation. We explored Lived Experience Panel members' preferences for notification.

Responses and recommendations from Panel members about notifying people involved in research

Notification was widely recognized as important by Lived Experience Panel members, and there were a range of thoughts about how this should be done, including the following:

- Some panel members said that the standard informed consent process is always needed.
- Don't talk down to people living with dementia.
- Be sure to acknowledge people living with dementia.
- Members of the research team should clearly introduce themselves.
- Researchers should not assume that people understand. They may need to provide information a few times to ensure understanding.
- It may be helpful to give people key information about the study multiple times, especially if they have memory loss or are forgetful.
- Discuss why the study is important.
- It would be helpful for notification to include an explanation of why the study used a waiver of informed consent.
- It is desirable to name funding sources for research projects.

- The timing and type of notification should be tailored based on the needs and preferences of the person living with dementia and their family. Members had various suggestions for how this might look:
    - Researchers should be sure to include people living with dementia in conversations because *"voice matters."*
    - A person living with dementia might want to have a family member present at the time they are notified about a study.
    - It may be necessary to speak privately with a care partner so as not to agitate the person living with dementia.
- There's no such thing as "too much" communication because communication builds trust and connection.
- Delays in notification can erode trust. Notify people as soon as possible.
- Plans for notification should account for communities and individuals who have historically not had the opportunity to consent to research participation.

Summary & reflection

There is agreement among the members of the Lived Experience Panel that more research is needed to improve dementia care and, by extension, the lives of people living with dementia and of their care partners. In some cases, this research can only be done if there is a waiver of informed consent; however, before a waiver is granted, it is essential to ensure adherence to ethical and regulatory standards.

Researchers must be trustworthy; this is not a goal or aspiration but a minimum requirement. This means both accounting for the lived experience of people living with dementia in the health care system—including experiences of stigma and discrimination—and designing studies in ways that are dementia-friendly. It also requires accounting for the experiences of members of diverse communities in the health care system and acknowledging the history of research abuses.

If a researcher is designing a study with a waiver of informed consent, it is important to ask for input from those with lived experience. An understanding of their views, attained through substantive consultation, can help inform researchers' understanding of key terms and concepts, such as "minimal risk" and "rights and welfare." Additionally, people living with dementia are embedded in relationships and communities, and the views of these stakeholders—such as family members, care partners, and others involved in the care of people living with dementia (e.g., paid caregivers)—should also be solicited when designing studies with waivers of informed consent.

Timeliness is important. If a study is conducted with a waiver of informed consent, the researchers should notify research participants as soon as possible. Information about the research should be

shared with people living with dementia, their family members and care partners, and other stakeholders in ways that respectfully promote their understanding.

Feedback from the Lived Experience Panel on this report

Members of the Lived Experience Panel were invited to review a draft of this report and provide written and verbal feedback on each of its elements. The text above has been iteratively revised to incorporate their feedback and additional suggestions and to capture their intent. Members emphasized their desire that the resulting report be disseminated widely and used to inform the design and conduct of studies using waivers of informed consent and, as relevant, research more broadly.

"The strong voices of the [Lived Experience Panel] members emphasized personhood and relationships above logistics or other barriers. This reminds researchers that, while families are desperate for more high-quality care, they are not willing to sacrifice their loved one's dignity in that process."

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