Welcome

Welcome, and thank you for participating in the Community Advisory Panel. Your group will be meeting in Austin, TX on July 29-30 from 8:30 AM to 5 PM each day. We are excited you can join us!

This booklet tells you what we will be talking about during this event and what you can expect. It also provides some background information for you to read and think about before the event.

What is a Community Advisory Panel?
Experts and elected officials need to understand the views and interests of the public to design good policy. “Community Advisory Panels” are events that bring together people from the community—who are experts in their own right—to learn about and discuss a particular policy issue.

What is the purpose of a Community Advisory Panel?
The purpose of a Community Advisory Panel is for people from many backgrounds to come together, learn about a particular issue, share their perspectives, and make recommendations about the issue to policymakers. By considering the informed opinions of people from the community, policymakers can get a better understanding of the concerns and interests of those who will be most affected by policy decisions. The diagram below gives an overview of the process.
What is the topic of this Community Advisory Panel?

During our time together, we will have a group discussion about one main topic. The topic we will be discussing is the “medical information commons.” A medical information commons is a virtual space where genetic, health, and other related information are stored, linked together, and shared electronically. Information in this virtual space (also called cyberspace) can be used in different ways, such as for research or making health care decisions. One common example of a virtual space is iCloud for Apple devices, which stores user pictures and videos, documents, music, emails, apps, and more.

We are asking for your input about how information in a medical information commons should be shared and used, and want you to think about one big question. There’s no right or wrong answer to this question, so don’t worry if you don’t feel like an “expert” in this area. The question is:

The purpose of the medical information commons is to:
- generate new knowledge through research,
- promote public health, and
- improve the delivery of health care.

To represent the public’s values and interests, what issues should policymakers take into account when personal, genetic and health information is shared with a medical information commons?

If you don’t fully understand the question or the idea of a medical information commons right now, that’s okay. There is more information in this booklet and the online video we sent you. We will also talk about it during the Community Advisory Panel.

What will happen during the Community Advisory Panel?

You will join about 30 other people from your local community for two days to learn about and discuss the ways genetic, health, and other related information is collected, shared, and used. You will hear from one another as well as some experts in this topic. There will be plenty of breaks and food will be provided.

We want to know what you think is best for everyone in your community and society overall. What is socially acceptable? What can we all live with? It may be natural to think about yourself and your family first, but we want to hear what you think is best for the larger community. It’s okay if we don’t all agree.

A facilitator will lead the discussion. The facilitator will make sure everyone gets a chance to speak and that we cover everything.
What do I need to do?

- Before the Community Advisory Panel, please look through this booklet. There is a glossary on Page 19 with definitions of words used in this booklet. You can refer to it as you read through the material.

- Before the Community Advisory Panel, please also watch the online video we created to help you understand the topics we will discuss. We included a link to the video in the email you received with this booklet.

- During the Community Advisory Panel, we ask that you come with an open mind and be ready to listen, learn, ask questions, and share your ideas. Some of the issues we discuss may be new to you but we will help you understand the topics. We want everyone to be part of the discussion. Remember – your input is important.

- When you share your thoughts during the group discussion, we will ask you to give reasons for your opinions. This helps everyone in the group understand why you feel the way you do.

Who is taking part in the Community Advisory Panel?
The Community Advisory Panel will include adults of all ages, from different backgrounds and with different life experiences. We want to have a good discussion with many different points of view. We will hold a total of 3 Community Advisory Panels across the country, in North Carolina, Texas, and California.

Who is conducting the Community Advisory Panel?
Two policy leaders: Amy McGuire from Baylor College of Medicine and Bob Cook-Deegan from Arizona State University recognized the need for public input and secured funding to hold 3 events. The American Institutes for Research (a nonpartisan, nonprofit organization also called A-I-R), planned and organized the events. The project is funded by the National Human Genome Research Institute (NHGRI), which is a part of the National Institutes of Health (NIH). The NIH is the main United States government agency responsible for funding health research. The team includes the three facilitators introduced on the next page.
What will we do with your input?
At the end of the Community Advisory Panels, we will share our findings with people who research, fund and design medical information commons, and people who make decisions about how health information is shared, like policymakers.

Meet your facilitators

Ela Pathak-Sen is a Director at Commotion. Her career has spanned over twenty-five years in the private, public and not-for-profit sectors. She has been an educator, manager and director, leading significant development and change projects. Ela operates from a value base that promotes principles of social justice with a strong commitment to community, wanting to make a difference through honest, open and co-operative working. She has developed and led community advisory panels worldwide. Ela also enjoys rummaging in antique shops, cooking and gardening.

Dierdre Gilmore is an experienced facilitator at AIR. She is passionate about working with the community to help answer difficult questions. Her work covers topics such as access to care, mental health, health insurance, care coordination, and health disparities. She has facilitated numerous community advisory panels across the country. Dierdre enjoys the outdoors and on most weekends is with her family at the beach or in the mountains.

Maureen Maurer is an experienced facilitator at AIR. Her work focuses on making sure the voices of patients and their families are included in decisions about health care and health research. She also leads a project that makes findings from research studies available in plain language. She has planned and facilitated many community advisory panels nationwide. Maureen enjoys spending time with her husband and two children in North Carolina. They have a large garden with all kinds of fruits and vegetables.
Background Information

To prepare you for the Community Advisory Panel
Sharing genetic, health, and related information

Sharing medical information is possible when genetic, health, and other related information is linked together in one place. The information may be given directly by individuals or have already been collected as part of the delivery of health care or as part of a research study. Since information is already being collected now and there are many possible uses for this information, it is important to understand the public’s views about information sharing.

Why information is shared

Sharing genetic, health, and other related information is a recognized need in the scientific and health care communities. The hope is that by combining all of this information from people in all states of health, researchers will have a more complete picture of human health and disease and how it changes over time. For example, if a researcher wants to know how many people get better from a treatment for diabetes, it is important to understand how many people have diabetes in a region and to know for sure who received treatment. Counting only people who are sick enough to go to the hospital would give an incomplete picture of diabetes care. Studying the full population is important to get accurate information to plan medical treatment. This type of information sharing across a population already happens in some parts of the U.S. and gives researchers and public health officials a resource they can use to conduct studies and plan for community health.

Sharing information across research studies is also important. Some government agencies or foundations that provide money for medical research require researchers to share the genetic, health, and other information they collect with other researchers so that the same information doesn’t need to be collected twice.

Medical information commons

When genetic, health, and other related information is shared and linked together in a virtual space, it is called a medical information commons. Information in this virtual space can be used for health research and to help guide the health care you receive in a clinic or hospital. Before sharing with others, information that can easily be used to identify someone (like name or date of birth) is removed.

It is more important than ever that we figure out when and how people want to share their information. That is why you have been asked to participate in this Community Advisory Panel. Your feedback can help shape how information will be shared and used going forward.
What types of information can be shared?

A medical information commons can include information from diverse groups of people, including people with known diseases and people without a diagnosed disease. Often, researchers stay connected with these people and ask them to contribute information over time, maybe for many years.

- Medical records: Individual medical history
- Personal information: Age, race/ethnicity
- Medical claims: Information about prescriptions
- Environmental information: Water samples
- Genetic information: May come from blood, saliva or tissue
- Lifestyle information: Food diary
- Other information: Wearable technology
- Medical Information Commons
Different types of information shared in a medical information commons

Examples of the different types of information that can be stored and shared in a medical information commons are described below.

**Personal information.** Personal information can include a person’s sex, gender identity, age, race/ethnicity, education, income, and employment.

**Medical records.** Health care providers—including doctors and hospitals—keep patient medical records. These records may include a person’s individual medical history, family medical history, social history such as smoking and drug or alcohol use, medical test results, prescribed medicines, health conditions, and treatments.

**Medical claims.** Health insurance companies keep records called medical claims when a person visits a doctor’s office or hospital. The records can include information such as a diagnosis, treatment, or filled prescriptions. Health insurance companies use medical claims to pay for health care services.

**Genetic information from samples of saliva, blood, and tissue.** These samples may be collected directly from people as part of a research study, or from samples collected during regular medical care such as laboratory testing or surgical biopsies. The samples contain DNA, the chemical code that tells the body what substances to make in order to function and grow. Everyone’s DNA is unique.

**Information about a person’s physical surroundings, air quality, or where they live (environment).** People may be asked for samples from or near their home, like water or soil. They may also be asked for information about where they live—like zip code or GPS location information—which could help researchers track a person’s exposure to toxic chemicals.

**Lifestyle and self-reported information.** Lifestyle includes an individual’s interests, opinions, activities and behaviors, or how they live. People might be asked to answer surveys, keep a food diary, or report their symptoms and quality of life.

**Other types of information.** Other types of information could include personal activity information from wearable mobile health technologies such as a Fitbit or Apple Watch. This information could be used to study how activity levels relate to medical and environmental information in terms of future disease risk.
How is information in a medical information commons protected?

There are already policies in place that may be used to protect people’s genetic, health, and other related information that is stored in a medical information commons. These policies were developed to make sure that typical information collected in medical records is kept confidential and help determine who can use the information. Below, we describe some of these protections.

**Federal laws.** Federal laws protect certain types of information stored in a medical information commons. Two examples are:

1. **HIPAA, or the Health Insurance Portability and Accountability Act,** which requires that an individual’s identifiable health information be kept confidential unless the person gives written permission to share it, and

2. **GINA, or the Genetic Information Nondiscrimination Act,** which prevents health insurers and many employers from discriminating against a person based on the person’s genetics.

**Laws for federally-funded research.** Research that is funded by the federal government must comply with government laws. These laws include requirements for the following:

**Informed consent.** Before people can participate in research, they must give their permission, or “consent.” Researchers need to describe the study fully and let people know about possible risks and benefits, and their rights and responsibilities as study participants. Once researchers are sure participants understand, participants are asked to sign a document that shows they give their informed consent.

**Institutional Review Boards (IRB).** IRBs monitor and review research involving humans to make sure it follows federal laws. IRBs are typically made up of doctors, nurses, researchers, experts in ethics, and members of the community. Approval from an IRB is required before most research involving humans can occur.
Removal of identifiable information. One way of protecting privacy is to remove all “identifiers” from personal information. Identifiers are pieces of information that reveal who a person is—such as name, birth date, and address. Identifiers are included in medical records. Some researchers use identifiers when they collect data for research studies, but later remove the identifiers from the data. This process is known as “de-identification.” The first table below shows an example of identifiable information collected from participants in a study (the examples below do not use real names.)

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Last name</th>
<th>First name</th>
<th>Sex</th>
<th>Date of birth</th>
<th>Date of diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Peterson</td>
<td>Andrew</td>
<td>Male</td>
<td>10/21/1945</td>
<td>11/30/1992</td>
</tr>
<tr>
<td>2</td>
<td>Johnson</td>
<td>Althea</td>
<td>Female</td>
<td>02/17/1930</td>
<td>01/25/1987</td>
</tr>
<tr>
<td>3</td>
<td>Hassan</td>
<td>Sahar</td>
<td>Female</td>
<td>06/05/1937</td>
<td>07/27/1990</td>
</tr>
<tr>
<td>4</td>
<td>Martinez</td>
<td>Rafael</td>
<td>Male</td>
<td>05/22/1940</td>
<td>03/09/1997</td>
</tr>
</tbody>
</table>

The next table shows what the information could look like after it is de-identified.

<table>
<thead>
<tr>
<th>Patient number</th>
<th>Sex</th>
<th>Age in 1990</th>
<th>Month and year disease was diagnosed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Male</td>
<td>45</td>
<td>11/1992</td>
</tr>
<tr>
<td>2</td>
<td>Female</td>
<td>60</td>
<td>01/1987</td>
</tr>
<tr>
<td>3</td>
<td>Female</td>
<td>53</td>
<td>07/1990</td>
</tr>
<tr>
<td>4</td>
<td>Male</td>
<td>50</td>
<td>03/1997</td>
</tr>
</tbody>
</table>

When researchers de-identify information, they keep a code that links the identifiable information to the de-identified information. That way, they can link the de-identified information back to the identifiable information if needed.

In other types of research, all identifiable information is removed permanently to protect patient confidentiality. When this happens, a patient’s record is said to be “anonymized.” There is no code that links the anonymized information back to any identifiable information.

Neither de-identification or anonymization provide perfect protection. It is important to note that both de-identified and anonymized information could still be used to identify a person, because the risk of “re-identification” (figuring out who someone really is) increases with more diverse sources of data. For example, it is highly unlikely, but not impossible, for a person to be identified if he has a rare disease diagnosis linked to zip code and GPS data.

Another way to “re-identify” a person is to link the genetic information in the medical information commons to other types of information that may be obtained from publicly available data sources. Since each person’s DNA is unique, anonymization is not an absolute protection against re-identification.
Under certain circumstances, researchers currently can share de-identified information without asking for permission first. Below we describe various issues related to how to balance the possible benefits of research with the possible risks to a person’s privacy.

Right now, people disagree about whether researchers and healthcare institutions should share people’s information without their specific permission or consent. This is because there are different opinions about how to balance the benefits and risks if the information cannot easily be used to identify the person it came from.

For example, if a researcher collects a blood sample from a person and does genetic analysis, should that researcher be able to share the person’s genetic information without her explicit consent? Or, should the researcher explicitly ask the person for permission to use her genetic information for research purposes?

If a person shares his information with a medical information commons, should he be able to specify which types of studies he wishes to participate in each time a new study is proposed by a researcher? Or should his decision to share his information mean that his information can be used for any studies that use information from the medical information commons?

**Types of consent**

**Opt-in consent** is when people **must give their consent** to be enrolled in a medical information commons. They are asked whether they want to sign up.

**Opt-out consent** is when people must specifically say they will not participate, or they will be enrolled automatically in a medical information commons.

**Dynamic consent** is when people can specify what information they want to make available in a medical information commons, and acceptable uses for their information.
Managing a medical information commons

Some people think IRBs should be the primary managers of information sharing. Others think that additional management is needed. People whose information is being shared could also play a central role in supervising how the information is accessed and used, either individually or as members of an advisory group.

But no matter how many policies and protections there are for people who share their information, it is important to note that a medical information commons, like any information system, cannot be fully safeguarded against criminal activity such as data hacking. While the chances are very small that data in a medical information commons could be used by hackers to identify an individual for criminal purposes (for example, to make money by selling information about people), it is possible.
Who is involved in information sharing?

There are many different individuals and groups involved in information sharing. Some of these include:

People. People can share their own information directly in some medical information commons. Individuals can share their genetic, health, and other related information with researchers doing studies, with online research communities or even with for-profit companies interested in developing new healthcare treatments. They can also choose who may have access to their information, select the kinds of studies that can use their information, and in some cases, they can do their own research.

Nonprofit organizations. Nonprofit organizations such as disease or research foundations usually fund medical information commons. These organizations may have access to the information by working with research partners. Some nonprofits also recruit participants directly and conduct independent research. These organizations often represent patients who have serious illnesses such as Alzheimer’s disease or a rare disease.

Government. The federal government funds the development of medical information commons that aim to advance understanding of disease, improve population health, and manage both rare and common diseases. Soon, the federal government will ask one million Americans representing all ages, races, and ethnicities to volunteer to share their genetic, environmental, lifestyle, and medical record information in what is known as the All of Us Research Program.

Universities. University-based researchers work to promote science and to improve clinical care through their research. They usually receive funding from outside sources such as foundations and the federal government to do this research. Several major breakthroughs about human health and disease have come from teams of university researchers. These teams often include researchers from different academic institutions and even different countries, all working together.
**Health plans and health systems.** Health plans provide health insurance, and they can gather information from the people they insure (called “members”). Health systems provide care to patients. Some organizations provide both health insurance and care. One example of this is Kaiser Permanente. With the appropriate permissions, health plans and health systems may link a person’s medical record information to biological samples obtained during the course of clinical care or as part of a research study.

**Drug companies and other for-profit health-related companies.** There are many different types of health-related for-profit companies that create, contribute to, or use medical information commons. For example, companies that make drugs and medical tests would like to use shared information to conduct research to help develop new personalized drugs and tests. There are related industries, such as mobile health companies and consumer genomic companies that are interested in combining information from mobile devices, health apps, and recreational genetic testing to also help develop new healthcare interventions. These include Apple, ancestry.com, Google, WebMD, and more.

Many of these organizations already have information from people who gave it to them for other purposes. The rules for how to share information among all of these new stakeholders are still being developed and different approaches are being tested.
## Examples of information sharing

### Framingham Heart Study

**Purpose:** The Framingham Heart Study started in 1948 and continues today in an effort to understand risk factors for cardiovascular disease (CVD). Study participants are followed for years and their health information is collected at multiple points throughout their involvement with the study.

**Sector:** Government & University – National Heart, Lung, and Blood Institute & Boston University

**Who contributes information?** Individuals who do not have symptoms of CVD and who give permission, to have their information used for research and shared with other researchers.

**How is information shared?** Information about study participants, including genetic information, is only available to qualified researchers who apply, sign an information sharing agreement, which is a contract, and are approved for access by review committees.

Framingham taught us much of what we know today about heart disease, such as that high cholesterol increases the risk of heart disease, and high blood pressure increases the risk of stroke.

**Website:** [https://www.framinghamheartstudy.org](https://www.framinghamheartstudy.org)

### Open Humans

**Purpose:** Open Humans is a program where the members of the public can share information obtained from different sources, including 23andMe and Fitbit, and choose research projects to be part of. It was started in 2015.

**Sector:** Nonprofit – Open Humans Foundation, Robert Wood Johnson Foundation, Knight Foundation

**Who contributes information?** Anyone interested in sharing their genetic report or information gathered by a wearable device, such as fitness tracker. Individuals have the option to create a profile describing who they are and upload their picture.

**How is information shared?** Individuals decide if they want to upload their information for public or private viewing. Public information can be downloaded by anyone from the Open Human website; private information requires the information-seeker to contact the person to request access.

Since Open Humans is still new, there are no findings to share yet.

**Website:** [https://www.openhumans.org](https://www.openhumans.org)
**Thinking about the benefits and concerns of a medical information commons**

<table>
<thead>
<tr>
<th>Possible CONCERNS of a medical information commons</th>
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<tbody>
<tr>
<td><strong>Potential loss of individual privacy and confidentiality.</strong></td>
</tr>
<tr>
<td><strong>Insurance and employment discrimination.</strong></td>
</tr>
<tr>
<td><strong>Information is used by industry to make drugs, tests and devices for profit.</strong></td>
</tr>
<tr>
<td><strong>Differences in health status that currently exist between different groups may worsen.</strong></td>
</tr>
<tr>
<td><strong>Group harms from particular types of studies.</strong></td>
</tr>
<tr>
<td><strong>Unintended results are learned as part of a study.</strong></td>
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</table>
### Possible BENEFITS of a medical information commons

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Description</th>
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<tbody>
<tr>
<td>Develop treatments and cures faster.</td>
<td>Researchers can study things like rare diseases, how genetic differences lead to cancer and other diseases, and how some people resist developing diseases. This information may lead to clinical trials of new treatments and targeted therapies.</td>
</tr>
<tr>
<td>Understand how environment and lifestyle can affect health.</td>
<td>Researchers can study how a person’s physical surroundings, how they live, and how their medical history and genetic profile work together to affect well-being.</td>
</tr>
<tr>
<td>Learn more about how to improve health outcomes for individuals and families who have a higher chance of getting certain diseases.</td>
<td>Genetic information can show whether an individual is at higher risk for certain diseases. People can work with their doctors to develop a plan to prevent or limit disease severity before it starts.</td>
</tr>
<tr>
<td>Learn about individual genetic makeup.</td>
<td>Some people are interested in learning about their genetic makeup in order to learn more about themselves and their family.</td>
</tr>
<tr>
<td>Develop tests to predict how an individual is likely to respond to a drug.</td>
<td>Depending on an individual’s genes, some drugs are less effective or may cause serious side effects. By understanding how an individual’s body processes drugs, researchers can develop tests that may be used by doctors before prescribing a drug to manage health conditions more effectively and avoid harmful side effects.</td>
</tr>
<tr>
<td>Protect public health.</td>
<td>Researchers use information gathered by public health databases to monitor and study diseases such as the flu, evaluate the success of health programs such as cancer screening, monitor safety of products such as artificial hip joints or pacemakers, and more.</td>
</tr>
<tr>
<td>Make lifestyle changes to improve overall health.</td>
<td>Based on the information available, individuals and their families can make decisions about changes in behaviors to improve their health and to stay healthy.</td>
</tr>
<tr>
<td>Provide direct benefits to participants and their communities.</td>
<td>Sponsors may pay people directly for their information, invest in community-related health care, or provide free access to treatments developed using their information.</td>
</tr>
</tbody>
</table>
Summary & discussion questions

Now that you’ve had the chance to learn more about how genetic, health, and other related information is shared and used, please take some time to think through these questions for the Community Advisory Panel.

To represent the public’s values and interests, what issues should policymakers take into account when personal, genetic and health information is shared with a medical information commons?

❖ What type of permission, if any, should be required from people before their information is shared?

❖ How should the public be involved when decisions are made about how people’s information is shared?

❖ What should people expect in return for sharing their information?

❖ What types of decisions about information sharing would lead to a trustworthy medical information commons?

❖ What types of management would lead to a trustworthy medical information commons?

❖ What uses of the information should be encouraged or forbidden?

❖ What are your hopes and concerns about information sharing?
Glossary

Anonymized information: In some types of medical records research, all identifiable information about people (such as names, birth dates, and addresses) is removed permanently to protect patient confidentiality. When identifiable information is removed permanently, the information is “anonymized.” There is no record that links the anonymized information back to any identifiable information.

Clinical research: Study of a drug, biologic or device in human subjects to determine its effect on health or disease.

De-identification: In some types of medical records research, researchers remove identifiable information about people (such as names, birth dates, and addresses), but keep a record that links back to the identifiable information. When there is a record that links back to the identifiable information, the information is “de-identified.” Researchers can use their record to link the de-identified information back to the identifiable information if needed.

DNA: The chemical name for the molecule that carries genetic instructions in all living things. DNA stands for Deoxyribonucleic Acid.¹

For profit: An organization that aims to make money through its work after paying all of its costs and expenses.

Genetic information: Information about your DNA, the results of genetic tests, family health history, use of genetic counseling, and participation in genetic research. Genetic information helps you know and understand health conditions that run in your family, as well as your risk for developing certain health conditions or having a child with certain conditions. Genetic information can help you make healthy lifestyle choices and important life and medical decisions. It also helps your doctor in providing you the best care possible.²

Genetic Information Nondiscrimination Act (GINA): is a federal law, passed in 2008, that prohibits discrimination against individuals in health insurance coverage and employment based on their genetic information. GINA does not apply to life, long-term care and disability insurance, or to employers with fewer than 15 employees.

Genome: All of a person’s genetic information.³

Genetic testing: Any procedure to determine whether a person has a gene that is associated with a disease or characteristic.

Governance: The use of power to direct behavior through law, policy, professional practice standards or social conventions.

Genetic disease: A disease caused (or strongly influenced) by abnormalities in an individual’s genetic material (genome). Some examples of disorders caused by DNA changes include cystic fibrosis and Huntington’s disease.

Medical information commons: A virtual space where genetic, health, and other related information is stored and shared.

Medical record: The record maintained by your doctors and other health care professionals, which includes information about your health history, medical visits, drugs you have been administered, test results, and other details of your medical care, such as x-rays or surgical reports. Health care professionals are required to enter and store complete, accurate records of their patients’ care. These records often include sensitive, personal information. U.S. law gives the patient a right to obtain a copy.

Nonpartisan: Not supporting one political group over another through words or actions.

Nonprofit: An organization that does not earn profits for its owners. Examples of nonprofits include charities, or educational, religious, and public service organizations.

Policymaker: Individual who helps decide on the rules or laws of an organization. These organizations can include state and federal governments.

Protected health information (PHI): The information collected by a doctor or other health care professional to identify an individual and decide how to provide them with medical care. Generally, personal health information, or PHI, includes demographic information, medical history, test results, and even insurance information.

Population health: The measures of health, including lack of disease, longevity and other factors, across the members of a group.

Precision medicine: The use of detailed information about a patient's genotype or level of gene expression and a patient's clinical information in order to select a medication, therapy or preventative measure that is particularly suited to that patient.

Stigmatization: To label as disgraceful or undesirable.

Virtual space: Also called cyberspace, a virtual space is an online environment facilitated by networked computers where information from many sources may be stored. One example of a virtual space is iCloud for Apple devices, which stores user pictures and videos, documents, music, emails, apps, and more. Another is the electronic database where the Department of Motor Vehicles keeps driver’s license information.