The Language of Consents Samples & Data

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The National Centralized Repository for Alzheimer's Disease and Related Dementias

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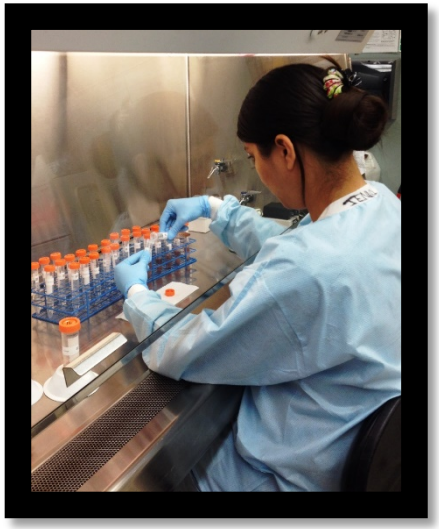

NCRAD

Topics

- Consent Language Recommendations
- Genomic Data Sharing
- GUIDs

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Consent Language

- All studies and institutions have different requirements but ***the broader the consent can be written initially, the more flexibility you will have in the future.***
- Goal today:
  - Review broad recommendations regarding genetics, samples, and data
  - Discuss ways to include consent language that provides the greatest flexibility for current and future research

Recommended Consent Key Points: Sample/Data Storage & Access

With all identifying information removed, the following may be done:

- The biological samples will be submitted to a Repository
- The data will be submitted to an approved database

Access to de-identified participant data and samples will be controlled.

- The biological samples and data will be shared with **approved** researchers.

Recommended Consent Key Points: Broad Use

The samples could be used for research into any type of disease

Reason:

- Historically, many consents were worded to focus on Alzheimer's disease or neurodegeneration
- By broadening the language, these samples and the resulting data can be used to ask a broader range of questions
- This has been very valuable for ongoing genetic studies where samples collected for other diseases/conditions are used as controls for AD

Recommended Consent Key Points: Wide Research Use

The sample and unidentified data will be available to researchers at hospitals, universities, and commercial organizations.

Reason:

- For profit/commercial organizations are usually the limitation that can restrict sample use.
- Restricting a group of researchers who can't use the samples could limit the opportunity for new discoveries.

Recommended Consent Key Points: Sample Storage

The samples will be stored indefinitely.

Reason:

- Some IRBs want to put limits for how long a sample can be stored. Sometimes tied to the end of the study or to a specific number of years.
- Try to avoid putting these limits on samples. Ongoing studies are actively using samples collected many years ago.
- Individuals with long term follow up (to death in some cases), make samples collected earlier in life even more valuable

Recommended Consent Key Points: Sequencing

When referencing genetic sequencing, do not restrict to one type of technology

Reason:

- If Whole Genome Sequencing (WGS) may be done at some point in future, new Common Rule requires stating that.
- Recommend not limiting language to WGS only:

  We *may* use biological samples collected as part of this study for genomic analyses such as whole genome sequencing. Whole genome sequencing involves determining the exact order of the base pairs (chemical letters) of your DNA. *Other genomic technologies may be used and continue to be developed.*

Recommended Consent Key Points: General Consent Elements

A possible risk from participation involves the loss of privacy

- **Include Genetic Risks: While genetic information is unique to subject, they do share genetic information with children, parents, brothers, sisters and other members of ethnic group etc.**

Taking part in this study is voluntary.

Recommended Consent Key Points: Withdrawal

If a subject withdraws, samples and data that have already been distributed for approved research will not be retrieved.

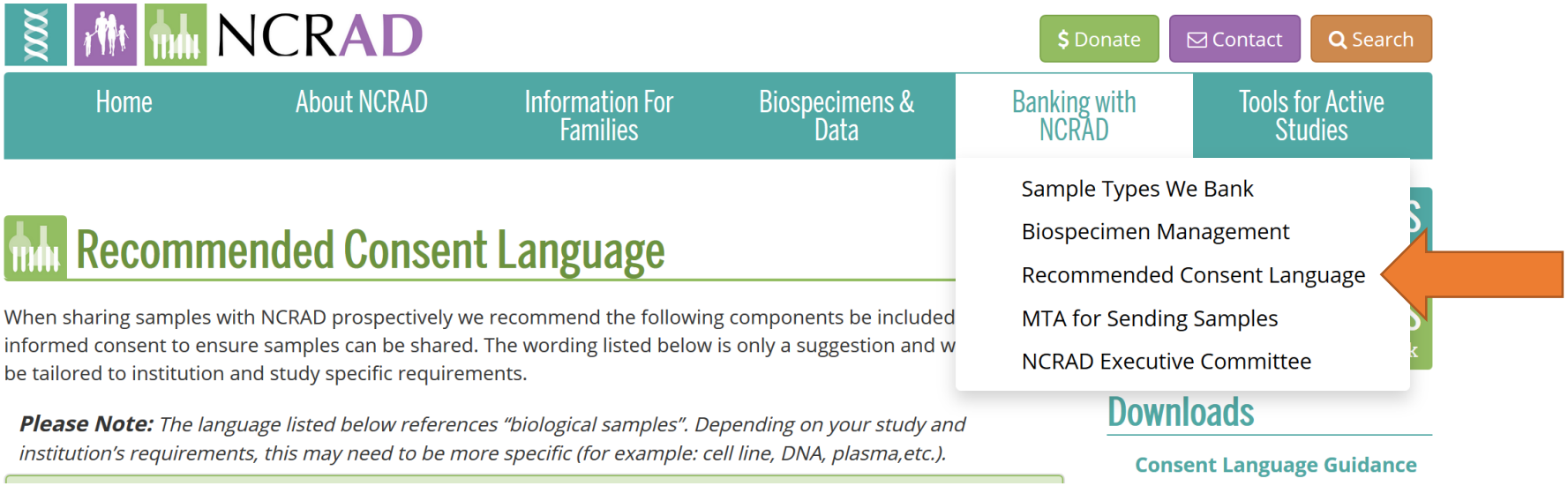
Reason:

- Once samples and data have been distributed, it is very difficult to be confident that they have been destroyed, if requested

Recommended Consent Key Points: General Recommendations

- GINA (Genetic Information Nondiscrimination Act) language should be included.
- If NIH funded, Certificate of Confidentiality language should be included.
- When possible, avoid the use of check boxes.
  - Tracking of the various responses possible when check boxes are present can be challenging and lead to potential errors.

NCRAD Recommended Consent



https://www.ncrad.org/recommended_consent_language.html

GDS

Genomic Data Sharing

NOT

Geriatric Depression Scale

NCRAD

Genomic Data Sharing

- Established in 2015 to set expectations regarding “broad and responsible” sharing of genomic research data
  - Developed due to advances in DNA sequencing, reduced cost
  - Data generated from one study can be used to explore a wide range of additional research questions.
- Institutional Certification shows how data can be shared
  - Does not require you to modify your consent form
  - Rather, it describes how subjects were consented

Genomic Data Sharing

Data Use Limitations

General Research Use	GRU	Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the dbGaP Collection.
Health/Medical/Biomedical	HMB	Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.
Disease-specific [list disease]	DS	Use of the data must be related to the specified disease.
Other		[ENTER CUSTOMIZED TEXT, IF APPLICABLE]

Additional modifiers to the standard DULs (e.g., Not-for-profit Use Only) can be indicated, if appropriate. Use of the modifiers should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population.

Data Use Limitation Modifiers (Optional)

IRB Approval Required	IRB	Requestor must provide documentation of local IRB approval.
Publication Required	PUB	Requestor agrees to make results of studies using the data available to the larger scientific community.
Collaboration Required	COL	Requestor must provide a letter of collaboration with the primary study investigator(s).
Not-for-profit Use Only	NPU	Use of the data is limited to not-for-profit organizations.
Methods	MDS	Use of the data includes methods development research (e.g., development and testing of software or algorithms).
Genetic Studies Only	GSO	Use of the data is limited to genetic studies only.

ADRCs and Genomic Data Sharing

2015

- Initial GDS documentation required from all ADRCs
- Specific to dbGaP
- Prior to NIH policy regarding genomic summary results
- New to IRBs

2018-2019

- Updated certification required from all ADRCs
- Beyond dbGaP
- Includes documentation of handling of genomic summary results
- IRBs now familiar

Genomic Data Sharing: Individual Level Data vs. Genomic Summary Results

The genomic summary results (GSR) from this study are only to be made available through ☐ controlled-access.

Explanation if controlled-access was selected for GSR.

- **Genomic Summary Results-Encourage NOT selecting this box in light of recent NIH policy** (NOT-OD-19-023)
  - Policy allows unrestricted access for genomic summary results
  - By not selecting, allowing to have summary statistics shared more broadly
    - p-values
    - Allele frequencies
    - Odds ratios
  - If dataset includes data from "sensitive group" (i.e. rare or stigmatizing traits), select controlled access and provide explanation

Genomic Data Sharing: Individual Level Data vs. Genomic Summary Results

- **Individual Level Data-Typically marked "Controlled Access"**

The individual-level data are to be made available through (check one)

◉ **controlled-access** [3]

○ **unrestricted access** [4]

If **unrestricted access** is marked, the data use limitations table on the following page(s) does not need to be completed.

NIH provides genomic summary results[5] (GSR) from most studies submitted to NIH-designated data repositories through unrestricted access. However, data from data sets considered to have particular 'sensitivities' related to individual privacy or potential for group harm (e.g., those with populations from isolated geographic regions, or with rare or potentially stigmatizing traits) may be designated as "sensitive" by .

In such cases, "controlled-access" should be checked below and a brief explanation for the sensitive designation should be provided. GSR from any such data sets will only be available through controlled-access.

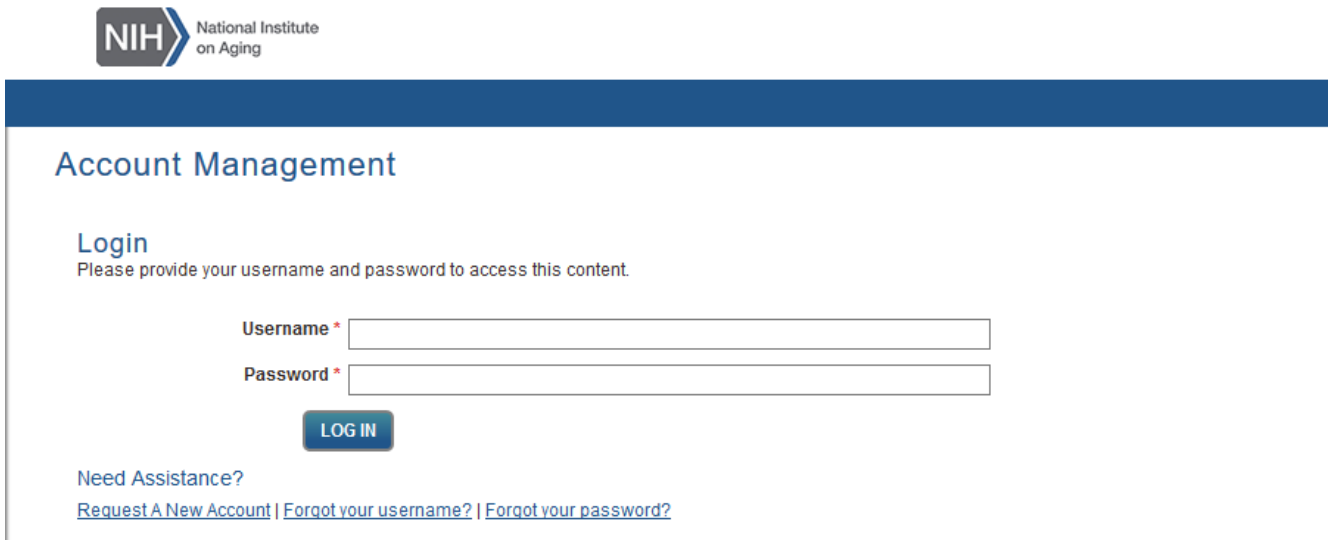
GUID
Global Unique Identifier

Why Would I Want a GUID?

- GUIDs are good!
- Universal subject ID that allows researchers to share data specific to a study participant without exposing PHI
- GUIDs provide a way to identify participants who are involved in multiple studies
  - Allows their samples and data to be linked across these studies
  - Avoid redundancy in large sequencing projects that use samples across multiple studies.

GUID-Globally Unique Identifiers

- GUID generated on **NIA website**
- GUID provided to NCRAD, ideally with sample form
- GUID uploaded to NACC in csv file



https://bricsguid.nia.nih.gov/portal/jsp/login.jsp

GUID-Globally Unique Identifiers

- To obtain a GUID, a center must collect the following information:
  - Complete legal given (first) name of subject at birth
  - Subject's middle name (if applicable)
  - Complete legal family (last) name of subject at birth
  - Day of birth
  - Month of birth
  - Year of birth
  - Name of city/municipality in which subject was born
  - Country of birth

***None of this identifiable information will be sent to NCRAD or NACC**

Questions?

- Regarding GDS:
  - Briana Vogel at NIAGADS
  - Briana.Vogel@pennmedicine.upenn.edu
- For NCRAD
  - Kaci Lacy: lacy@iu.edu
  - Kelley Faber: kelfaber@iu.edu
  - General: alzstudy@iu.edu or 800-526-2839

Acknowledgement

- NCRAD Executive Committee
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- NIA
- Alzheimer Disease Centers
- NACC
- NIAGADS
- ADGC
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NCRAD Staff