DECISION TREE #2

Research Involving Secondary Use of Information/Biospecimens

Is the information/biospecimens about or from living individuals?

NO → Individuals are not living

YES → Individuals are living

Not Human Subjects Research, IRB APPROVAL NOT REQUIRED

Is the information/biospecimens publicly available?

— YES → Not Human Subjects Research, IRB APPROVAL NOT REQUIRED

— NO →

Is the information/biospecimens:
- Unidentifiable information/biospecimens obtained from a provider that is prohibited from releasing identifiers by established regulations or policies; or
- unidentifiable information/biospecimens obtained from a commercial provider; or
- unidentifiable human cell lines obtained from a commercial provider (e.g. ATCC); or
- human cells about which all information has been published?

YES → Can the *provider* of the data link the information/biospecimens, directly or indirectly, to identifiable living

NO → Not Human Subjects Research, IRB APPROVAL NOT REQUIRED

Can the *provider* of the data link the information/biospecimens, directly or indirectly, to identifiable living

— **NO** → Not Human Subjects Research, IRB APPROVAL NOT REQUIRED

— **YES** → Does the *provider* meet the definition of an "investigator" in the recipient's research?

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— **NO** → *Provider* is "solely providing" → Is a code linking identifiable information to living individuals provided with the information/biospecimens?

— **YES** → *Provider* is collaborating in recipient's research → YES

Is a code linking identifiable information to living individuals provided with the information/biospecimens?

— **NO** → Not Human Subjects Research, IRB APPROVAL NOT REQUIRED

— **YES** → Can the *recipient* readily ascertain the identities...

Is the information/biospecimens (NO branch from the bulleted box):

Were/will the information/biospecimens (be) collected specifically for the proposed research through an interaction or intervention with living individuals?

— **NO** → Can the *recipient* link the information/biospecimens **directly** to identifiable living individuals?

— **YES** → IRB APPROVAL OR DETERMINATION OF EXEMPTION IS REQUIRED

Can the *recipient* link the information/biospecimens **directly** to identifiable living individuals?

— **NO** → Can the *recipient* readily ascertain the identities...

— **YES** → IRB APPROVAL OR DETERMINATION OF EXEMPTION IS REQUIRED

Can the *recipient* readily ascertain the identities of the individuals to whom the information/biospecimens pertain? Examples of situations in which the recipient cannot link the information/biospecimens to living individuals include:
- The key to decipher the code is destroyed before the research beings; OR
- The investigators and the holder of the key to the code enter into an agreement preventing the release of the key to investigators under any circumstances; OR
- There are IRB-approved written policies in place preventing the release of the key under any circumstances; OR
- There are other legal requirements prohibiting the release of the key under any circumstances.

— **NO** → Not Human Subjects Research, IRB APPROVAL NOT REQUIRED

— **YES** → IRB APPROVAL OR DETERMINATION OF EXEMPTION IS REQUIRED

IRB APPROVAL OR DETERMINATION OF EXEMPTION IS REQUIRED before the study may begin. An IRB application may be completed in IRBManager. Questions? Contact IRB@iastate.edu.