IRB Considerations for Privacy and Confidentiality Safeguards (Final Rule Preamble)

• Extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified

• Use of the information

• Extent to which the information will be shared or transferred to a third party or otherwise disclosed or released

• Likely retention period or life of the information

• Security controls that are in place to protect the confidentiality and integrity of the information

• Potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption