Research in Europe, GDPR, and Consent

From:
https://www.mwe.com/en/thought-leadership/publications/2018/02/does-gdpr-regulate-research-studies-united-states

If a research organization relies upon an individual's consent as the basis for processing Personal Data for a research study, what consent requirements apply under GDPR?

GDPR permits an organization to rely upon consent from research subjects as a lawful basis for processing Personal Data for research purposes. As discussed below, to obtain a valid consent to processing an individual's Personal Data for research purposes under GDPR, the individual's consent must be freely given, specific, informed and unambiguous agreement to the processing:

Freely given: The individual must have a realistic choice, or the realistic ability to refuse or withdraw consent without detriment. Similar to US law, coerced consents are not compliant with GDPR.

- **Specific**: The consent must include a specific, transparent statement of each purpose. The extent to which GDPR permits research organizations to obtain less than a specific and granular consent to process Personal Data for future research purposes, as now contemplated by the 2017 changes to the federal Common Rule that are now scheduled to become effective on July 1, 2018, is discussed further in the next section below and in our recent publication regarding these Common Rule changes, *HHS Finalizes Toned-Down Version of Common Rule Overhaul*.
- **Informed**: An individual must be informed of the nature and extent to which the individual is consenting.
- **Unambiguous**: GDPR requires a statement or "clear affirmative act" (*e.g.*, checking an unchecked box in an online context) that indicates the individual has agreed to the proposed processing activities. Silence, pre-ticked boxes and inactivity are insufficient for purposes of consent.

In addition, for the processing of genetic data, biometric data, health data and certain other sensitive categories of Personal Data (Sensitive Personal Data), the individual's consent must be "explicit." The GDPR does not define "explicit" consent or describe how it compares to the "clear affirmative act" requirement of a regular consent to process Personal Data. However, GDPR interpretive guidance issued on November 28, 2017 (Article 29 Consent Guidance) issued by the Article 29 Data Protection Working Party, an EU advisory body, includes several examples of explicit consent: a hand-written signature, an electronic signature, an uploaded scanned document carrying a signature or two-stage verification of consent where individual must click on a verification link by email or text message after initially consenting.

May a research organization process Personal Data for future uses beyond the purpose for which consent was initially obtained?

Similar to the liberalized consent requirements for future use of data for research purposes in the amended version of the Common Rule adopted in 2017, GDPR Recital 33 suggests that research organizations may rely upon an individual's consent at a more general level for the use of Personal Data for future research purposes that cannot be fully specified at the outset of a research study. Recital 33 provides as follows:

''It is often not possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection. Therefore, data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognized ethical standards for scientific research. Data subjects should have the opportunity to give their consent only to certain areas of research or parts of research projects to the extent allowed by the intended purpose.''

However, the Article 29 Consent Guidance includes guidance with respect to specificity of consent to future research uses that seems more restrictive than GDPR Recital 33 and the 2017 Common Rule revisions. The Guidance suggests that a broad consent to unclear future research purposes may not suffice and that GDPR requires a consent with a "well-described" purpose statement for each stage of research or other safeguards. Such safeguards may include data minimization, anonymization, data security or transparent communications to individuals as research activities progress. Accordingly, a research organization should carefully analyze the adequacy of proposed consent forms that seek broad consents to use Personal Data for undefined research purposes.