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10-3. Informed Consent Waiver

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10-3.1* This request is for:

Select all that apply:

- [x] Waiver – General - ALL of the project
- [x] Waiver – General - PART of the project (A waiver is no longer required for screening/recruitment purposes.)
- [ ] Alteration to required element(s) – General - ALL of the project
- [ ] Alteration to required element(s) - General - PART of the project
- [ ] Waiver or alteration - Only applies to state/local government research or demonstration project designed to study, evaluate, or otherwise examine:
  - Public benefit or service program
  - Procedures for obtaining benefits/services under those programs
  - Possible changes in or alternatives in those programs or procedures, or
  - Possible changes in methods or levels of payment for benefits under those programs
- [ ] Waiver (OHRP)/ exception (FDA) - Only applies to Planned Emergency Research with Exception From Informed Consent (EFIC).

  Contact the IRB if you think this category may apply. Upload a separate document justifying the requirements for this waiver. OHRP guidance and FDA regulation permit informed consent waiver under a specialized circumstances for a strictly limited class of research, involving research activities that may be carried out in human subjects who are in need of emergency therapy and for whom, because of the subjects' medical condition and the unavailability of legally authorized representatives of the subjects, no legally effective informed consent can be obtained.

10-3.1.1 If this request is for PART of the project, identify the specific research procedures (e.g., screening interview) and/or the specific subject populations (e.g., parents of child-subjects) involved.

OFTEN acceptable to request waiver for ALL of the project to access clinical data/specimens both past and future.

AT A MINIMUM, though, request waiver for PART of the project if you use medical records to identify potential subjects.

EACH sub-question in 10-3.2 should be answered specifically.

10-3.1.2 Explain any requested alterations to the informed consent process.

10-3.2* This request is for:

- [x] The research involves no more than minimal risk to the subjects. (i)

Explain

Points you might include (as applicable):

*no direct subject involvement,
*no risks of physical harm or discomfort.

☑ Research could not practicably (i.e., feasibly) be carried out without the waiver or alteration. (ii)

Explain

WHY is obtaining consent not feasible? Points you might include (as applicable):

*time from study team members,
*cost of phone calls/mailings/visits,
*no funding for this study,
*cannot obtain FULL dataset if consent is obtained from some subjects and not others.

☑ If the research involves identifiable private information or biospecimens, the research could not be practicably carried out without using such information or biospecimens in an identifiable format. (iii)

Explain

WHY is it NOT feasible to use data/biospecimens that have already been "coded" or "de-identified" by an 'honest broker'?

If this is a MiChart medical record review, why will DataDirect https://datadirect.med.umich.edu/ or another service from the Data Office for Clinical & Translational Research https://research.medicine.umich.edu/office-research/data-office-clinical-and-translational-research NOT suffice?

If the provider will only provide identifiable information, why can you NOT anonymize (de-identify) data/biospecimens immediately upon receipt?

Possible answers include a need to correlate data from multiple sources (which requires retaining identifiers at least until data collection is complete) or plans to re-contact (although this is rare for secondary use-only research).

☑ The waiver or alteration will not adversely affect the rights and welfare of the subjects. (iv)

Explain

Points you might include (as applicable):

*data collected is not particularly sensitive,
*no expectation that use of data could affect subjects' physical, emotional well-being,
*no expectation that use of data coud affect subjects' personal or professional relationships or insurability.

☑ Whenever appropriate, the subjects or their Legally Authorized Representative will be provided with additional pertinent information after participation. (v)

Explain

Explain your plans. In SOME cases, there may be no reasonable expectation that you could uncover "pertinent information": if so, justify this.

In MANY secondary use analyses, there is no plan to recontact subjects under any circumstances

- Specialized waiver or alteration for state/local public benefit and service programs -- see (e)
- Screening, recruiting, or determining eligibility without formal IRB waiver -- see (g)

Planned Emergency Research References:

- Informed Consent Requirements in Emergency Research (OPRR Letter, 1996)
- FDA Information Sheet Exception from Informed Consent for Studies Conducted in Emergency Settings
- IRBMED Position Statement 2007 on Allowing Exception From Informed Consent For Emergency Care Research
- U-MIC presentation "Exception from Informed Consent Requirements for Emergency Research"

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