IDR/IRB Overlapping Circles

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Uses of IDR

- IDR used to identify records that meet inclusion criteria. Does not include contacting subjects.
  - Only MRNs requested
  - Identification of MRNs and additional data requested
    - Data from MR requested from IDR Honest Broker services
      - •IDR releases a data set with no identifiers (confidentiality agreement needed)
      - •IDR releases a limited data set as defined by HIPAA (dates and zip codes are included)

- IDR used to identify subjects including contacting them: Consent2share
  - IDR releases contact information of people who may qualify for study

- Other uses?

What Does IDR Need?

- Clear statement of data elements that IDR should provide to researchers
- How do we get there?
  - Review types and corresponding sources of truth

IRB Review Types

- Start with review type and see if waivers are approved or there is consent/authorizations
  - Full Board and Expedited
  - Chart Review

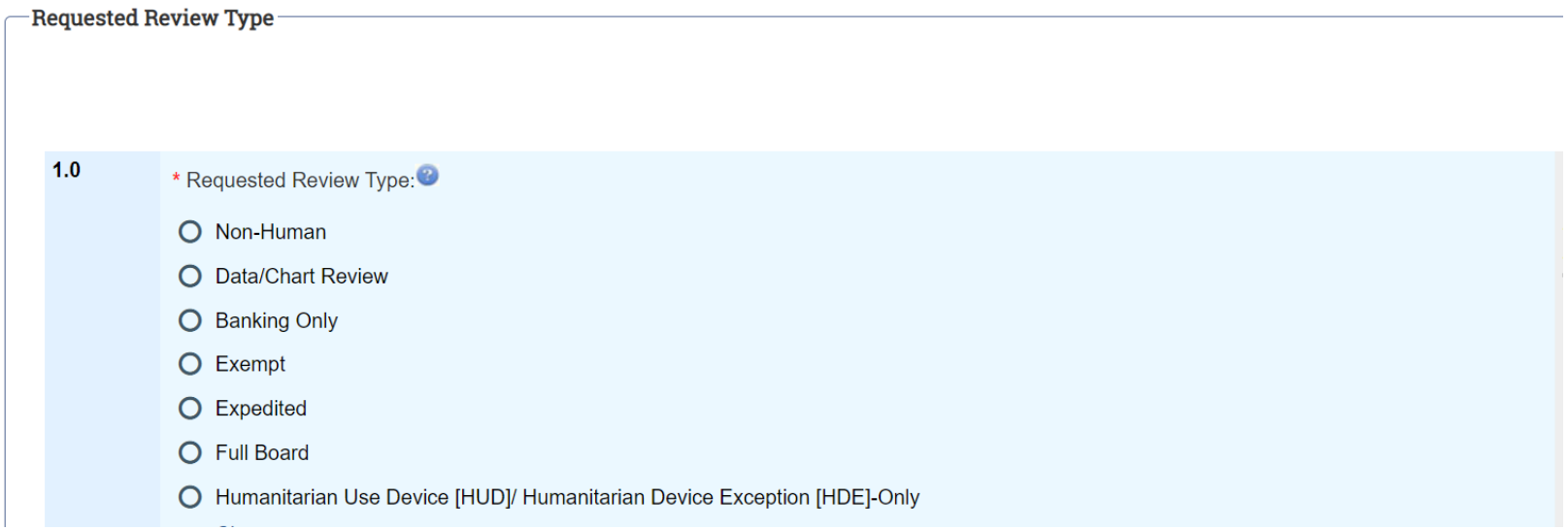


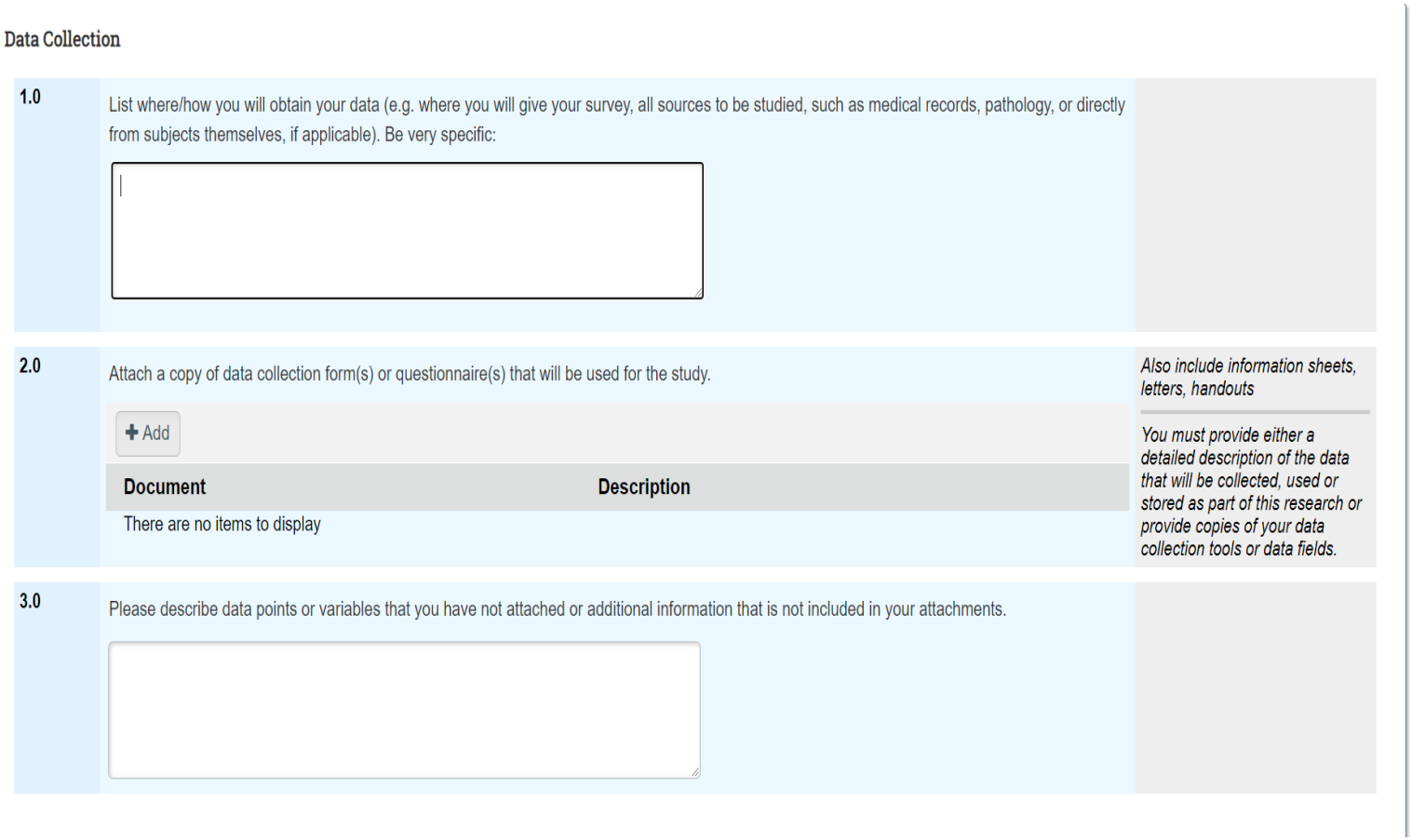
Chart Reviews

Two flavors: Exempt and expedited

- **Exempt**
  - **4ii** – rare these days.
    - No link between data and identifiers in the research record. IDR either gives the complete data set or only gives them the list of MRNs that meet criteria with no other data. We then require them to access the record, redact the MRN from their list and then record the study data they are approved to use.
  - **4iii** – common type.
    - Identifiers can be in the research record and the link between them and data can be maintained through the end of the study.
- **Expedited 5** which usually allows for everything in category 4iii plus they are getting identifiable tissue or specimens.

Data Collection Smartform Source of Truth- Chart Reviews

This page is the source of truth for what IDR can dispense.



Data Collection

1.0 List where/how you will obtain your data (e.g. where you will give your survey, all sources to be studied, such as medical records, pathology, or directly from subjects themselves, if applicable). Be very specific:

2.0 Attach a copy of data collection form(s) or questionnaire(s) that will be used for the study.

Also include information sheets, letters, handouts

+ Add

Document	Description
There are no items to display	

You must provide either a detailed description of the data that will be collected, used or stored as part of this research or provide copies of your data collection tools or data fields.

3.0 Please describe data points or variables that you have not attached or additional information that is not included in your attachments.

HIPAA Waiver of Authorization

- Very general, involves specific identifiers and general medical information (categories), should not be identical to the data collection sheet but consistent with it.
- This page must inform you actions but cannot guide tehm

HIPAA Waiver of Authorization

1.0

* What protected health information will you collect, create, use, or disclose *(disclose = outside the covered entity)*, **under this waiver**?

Name

Treatment diagnosis

Treatment dates

Treatment details

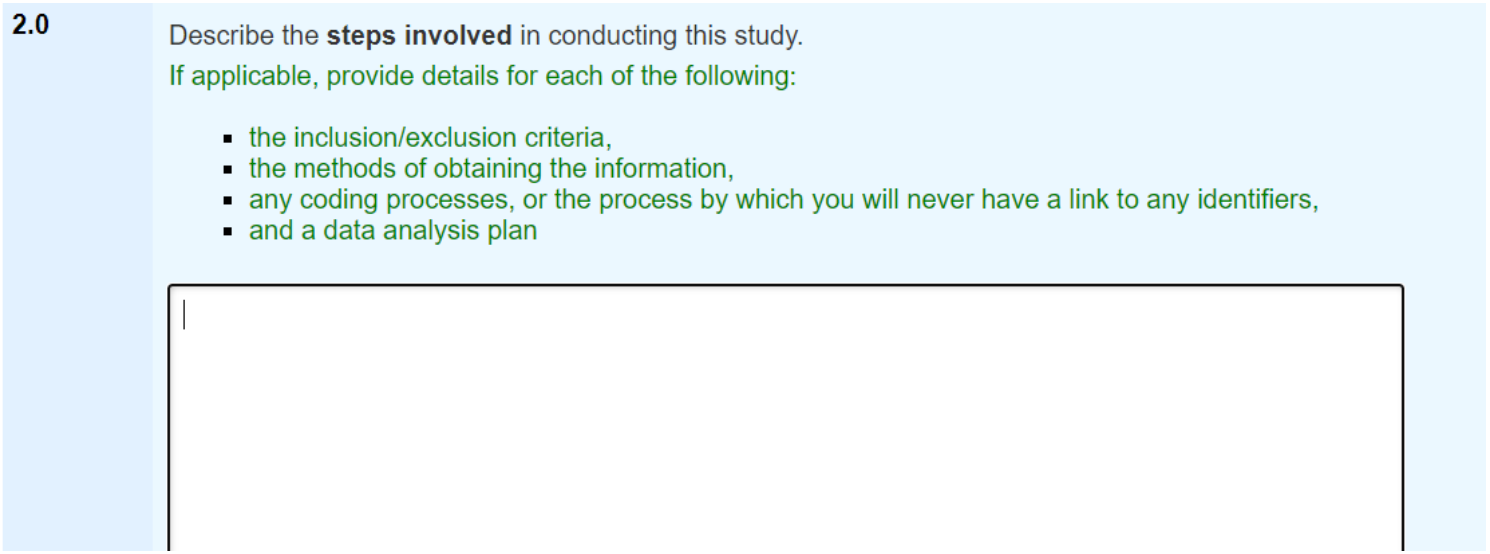
Current disease or death status

Date of death, if relevant

NOTE 1: Do not list the information that you are collecting, using, disclosing under an authorization signed by the subject. This section is just for information collected/used/disclosed under this waiver.

NOTE 2: *(click for suggested language)*

Study Description SmartForm



- Any information about data flow can be found on this page.
- Also, any infromation that would normaly be contained in a protocol (e.g. description of the IDR activities that might include de-identifying or data/images) will be specified here.

Expedited and Full Board Relevant SmartForms

- Two uses of IDR: recruitment and/or data supply
- Haveto pay attention to the recruitment SmartForm (is Consent2Share selected)
- Consent/authorization is in play, subject authorizes use of PHI
- Information sources and identifiers SmartForm, what identifiers are selected?
- Sometimes there is a data collection form

How Many Records to Release – Enrollment Details SmartForm

Enrolled subject = subject who has signed informed consent or who is enrolled under a waiver

- Do not give more than they are approved in TOTAL (a+b+c).
  - So,If they are approved for 100 but need 130 becaue of screen failures, they need to submit a revision to increase the total enrollment number.

	# of Subjects
* a. How many subjects do you need to complete the study?	
* b. How many additional subjects will be enrolled/included in this project but might discontinue participation in the study before completing all study interventions/interactions (either due to adverse event, withdrawal, etc.)?	
* c. If 1.1 (above) is "Yes", how many additional subjects do you believe will need undergo these screening procedures and will not count toward the numbers listed in questions a and b above (these subjects would be screen failures)?	
TOTAL (a+b+c) =	**0**

Recruitment SmartForm

2.0 Describe who will identify and recruit subjects for this research:

3.0 How will the individual(s), listed above, identify and recruit subjects for this research?

Recruitment SmartForm

4.0 Indicate if you will use any of the following methods to identify and recruit subjects: (check all that apply)

- ☐ Medical Records
- ☐ Clinical Database
- ☐ Inpatient Population
- ☐ Patient care meetings, rounds, tumor board meetings, etc.
- ☐ Outpatient Population: Pre-review of outpatient records or lists or appointments prior to seeing the patient in clinic
- ☐ Outpatient Population: Patients seen in clinics during normal appointments and approached about research
- ☐ Advertising
- ☐ Referrals – clinicians outside your practice cannot send you contact information for their patients without a signed authorization from the subject. Make sure you receive a signed authorization or consent for every subject referred to you
- ☐ Undergraduate Student Pool (e.g. SONA)
- ☐ Research Database/other IRB approved protocol
- ☐ Healthstreet
- ☐ StudyConnect
- ☐ Consent2Share
- ☐ Research Match
- ☐ Other

4.1 If "Research Database(s)", provide, Name(s), IRB#(s), Description:

+ Add

Name	IRB Number	Description
There are no items to display		

4.2 If "Other" methods, Specify:

Information Sources and Identifiers SmartForm

1.0 Identify the sources where you will get your information/data that is being collected:

- [ ] Subject
- [ ] Questionnaires or Interviews
- [ ] Mental Health Records
- [ ] Hospital or Medical Records
- [ ] Data Previously Collected for Research Purposes
- [ ] Biological Samples
- [ ] DNA Samples
- [ ] Research Database
- [ ] Clinical Database
- [ ] Other

1.1 If "Other", specify:

2.0 Please review the list of forms and/or questionnaire(s) you have already provided:

There are no items to display

Attach a copy of any **additional** data collection form(s) or questionnaire(s) that will be used for the study.

+ Add

Information Sources and Identifiers

3.0 Check all Identifiers which will be used or collected:

- [ ] Social Security Number
- [ ] Telephone Numbers
- [ ] Full Face Photographic Image
- [ ] Email Address
- [ ] Medical Record Identifiers
- [ ] Name
- [ ] Dates
- [ ] Geographic subdivision smaller than a state or the first three digits of a zip code
- [ ] Facsimile numbers
- [ ] Health Plan Numbers
- [ ] Account Numbers
- [ ] Certificate/License Numbers
- [ ] Vehicle Identifiers
- [ ] Device Identifiers
- [ ] Web URLs
- [ ] IP Address Numbers
- [ ] Biometric Identifiers
- [ ] Any other unique identifying number, characteristic, or code.

3.1 If Other, specify:

Notions of Interest

Identifiable information – anything that has one or more of 18 HIPAA identifiers

PHI – Identifiable information couppled with medical information about the patient which is created by the covered entity. (e.g. MR information))

Medical history (provider information not part of it, distinguish between medical history and patient record)

QUESTIONS