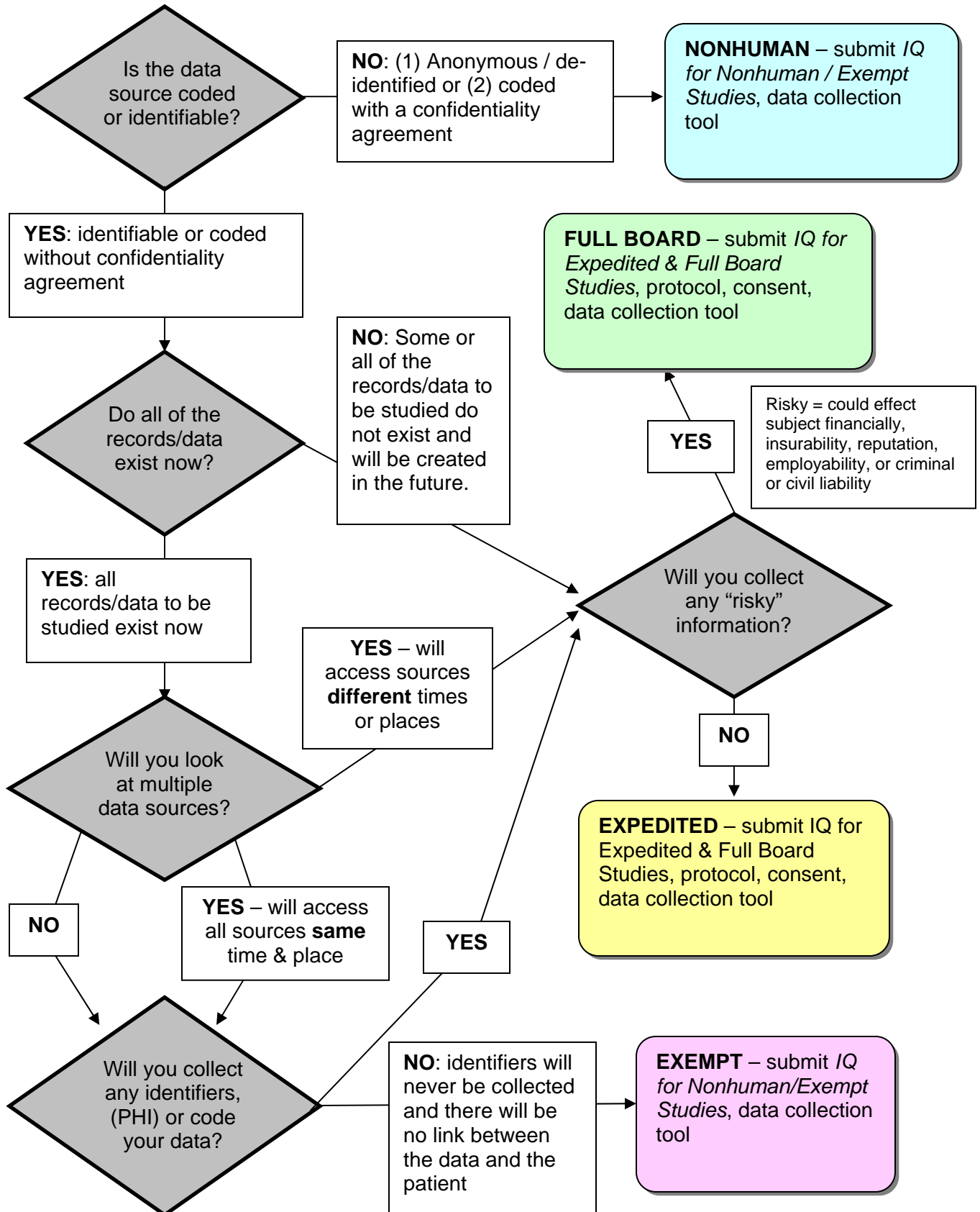




**Conducting Research on Medical Records, Chart Review,  
or other Existing Data (IRB approved Databank, publicly available data, etc)**



**Conducting Research on Medical Records, Chart Review,  
or other Existing Data** (IRB approved Databank, publicly available data, etc)

|  |  |  |
|--|--|--|
| <b>NONHUMAN</b>  | Researcher obtains data from IRB Approved Databank, publicly available data, etc:  | <p>Increasing Subject Involvement or Risk</p>  <p>Therefore more protection needed. IRB must ask more questions, require more (e.g. obtain consent)</p> |
|  | <p>AND the data that is received is either</p> <p>(1) anonymous (no identifiers)</p> <p>OR</p> <p>(2) coded and you obtain a “Confidentiality Agreement” (<a href="http://irb.ufl.edu/docs/specimen-agreement.doc">http://irb.ufl.edu/docs/specimen-agreement.doc</a>) with the entity providing the data</p> <p><i><b>NOTE:</b> If the data you receive contains any identifiers (name, social security #, zip code, etc) proceed to Exempt or Expedite review.</i></p>   |  |
| <p><b>Submit</b> the Introductory Questionnaire for Nonhuman/Exempt Studies (<a href="http://irb.ufl.edu/docs/IQ-short.doc">http://irb.ufl.edu/docs/IQ-short.doc</a>) and data collection tools.</p> <p>If data is coded with confidentiality agreement – you can request future or additional data.</p> <p>One time approval (need to get approval for any changes, should report when the study is completed).</p> |  |  |
| Researcher sees identifiers in medical record, clinical charts, or other data source   |  |  |
| <b>EXEMPT</b>  | <p>BUT all three of the following are true:</p> <p>(1) <b>all</b> of the records/information that will be examined <b>exists at the time the researcher submits his/her paperwork to the IRB</b> (you are not interested in and will never look at records/information that will come into existence after the submission date);</p> <p>(2) the researcher obtains data from either (a) a single data source or (b) multiple sources but certifies that all sources will all be accessed at the same time and place; AND</p> <p>(3) <b>the researcher anonymizes/de-identifies the data as he/she collects it</b> – there is never a way to look at the research data and identify who it belongs to. This includes no links or codes, temporary or otherwise.</p> |  |
|  | <p><b>Submit</b> the Introductory Questionnaire for Nonhuman/Exempt Studies (<a href="http://irb.ufl.edu/docs/IQ-short.doc">http://irb.ufl.edu/docs/IQ-short.doc</a>) and data collection tools.</p> <p>One time approval (need to get approval for any changes, should report when the study is completed).</p> <p><i>Cannot revise study to add future records or correlate new data to previously examined records.</i></p>   |  |
|  |  |  |

**Conducting Research on Medical Records, Chart Review,  
or other Existing Data** (IRB approved Databank, publicly available data, etc)

|  |   |  |
|--|---|--|
| <b>Expedited</b>   | Researcher sees identifiers in medical record, clinical charts, or other data source  | <p>Increasing<br/>Subject<br/>Involvement or<br/>Risk</p>  <p>Therefore more<br/>protection<br/>needed. IRB<br/>must ask more<br/>questions,<br/>require more<br/>(e.g. obtain<br/>consent)</p> |
|  | <p>AND one or more of the following are true</p> <ul style="list-style-type: none"> <li>(1) the researcher is obtaining data from more than one source</li> <li>(2) some or all of the records/information may exist after the researcher submits to the IRB (“future records”) <ul style="list-style-type: none"> <li>a. note: you may need to seek/obtain consent from subjects in order to look at their future records.</li> </ul> </li> <li>(3) You want to keep identifiers or code the data in order to possibly add/correlate additional data points at a later date, etc.</li> <li>(4) Information collected is “minimal risk” and will not (a) place the subjects at risk of civil or criminal liability, or (b) affect insurability, employability, reputation, or financial standing. (you cannot collect information about HIV status, drug use, criminal activities, etc).</li> </ul> |  |
| <p>Submit the Introductory Questionnaire for Full Board and Expedited Studies (<a href="http://irb.ufl.edu/docs/frm-iq.doc">http://irb.ufl.edu/docs/frm-iq.doc</a>) with appropriate IQ Addenda, Protocol (<a href="http://irb.ufl.edu/docs/frm-prot.doc">http://irb.ufl.edu/docs/frm-prot.doc</a>), data collection tools, possibly Informed Consent Forms (<a href="http://irb.ufl.edu/irb01/forms2.htm">http://irb.ufl.edu/irb01/forms2.htm</a>), and other pertinent items.</p> <p>Study is approved for a maximum of one year. Need to submit a Continuing Review Report at least 3 to 4 weeks before the study expires. Need to obtain approval for any changes, problems, and close the study when completed.</p> |   |  |
| Researcher sees identifiers in medical record, clinical charts, or other data source   |   |  |
| <b>Full Board</b>  | <p>AND collects data that</p> <ul style="list-style-type: none"> <li>(1) You want to keep identifiers or code the data (e.g. in order to possibly add/correlate additional data points at a later date, etc.)</li> <li>(2) is “<b>greater than minimal risk</b>” because it could (a) place the subjects at risk of civil or criminal liability, and/or (b) affect insurability, employability, reputation, or financial standing</li> </ul>  |  |
|  | <p>Submit the Introductory Questionnaire for Full Board and Expedited Studies (<a href="http://irb.ufl.edu/docs/frm-iq.doc">http://irb.ufl.edu/docs/frm-iq.doc</a>) with appropriate IQ Addenda, Protocol (<a href="http://irb.ufl.edu/docs/frm-prot.doc">http://irb.ufl.edu/docs/frm-prot.doc</a>), data collection tools, possibly Informed Consent Forms (<a href="http://irb.ufl.edu/irb01/forms2.htm">http://irb.ufl.edu/irb01/forms2.htm</a>), and other pertinent items.</p> <p>Study is approved for a maximum of one year. Need to submit a Continuing Review Report at least 3 to 4 weeks before the study expires. Need to obtain approval for any changes, problems, and close the study when completed.</p>  |  |