



## FORM 01: BRANY IRB – CONFLICT DISCLOSURE STATEMENT

### INSTRUCTIONS

All members of the study team (i.e. **key study personnel**) must complete and submit this form. Read the definitions below, then complete page 2. Be sure to both print and sign/date your name where indicated.

### DEFINITIONS

- **Financial interest related to the research** – A financial interest in the sponsor, product, or service being tested, or anything of monetary value from a financially interested company, including but not limited to:
  - Officer's or Director's fees
  - Consulting fees
  - Compensation for service on an Advisory Board (including scientific advisory boards)
  - Honoraria for lectures or teaching
  - Gifts
  - Other emoluments or "in kind" compensation such as travel and entertainment from a financially interested company (including those from a third party the original source is a financially interested company), for any services not directly related to the reasonable costs of conducting the research as specified in the research agreement
  - Compensation related to the research whose amount might be affected by the outcome of the research
  - Equity interest of any kind and in any amount in a non-publicly or publicly traded Financially Interested Company (e.g., stocks, stock options, convertible notes, other ownership interests), including those for which the value cannot be determined through reference to publicly available prices, those for which the value may be affected by the outcome of the research, and those which represent a 5% or more interest in any one single entity
  - Intellectual property related to the proposed research
  - License fees, technology transfers, and/or current and future royalties from patents and copyrights
  - Board or executive relationships related to the research (regardless of compensation)
  - Paid/reimbursed travel for research funded or supported by an HHS agency, meaning the occurrence and value of any paid/sponsored (i.e., sponsored travel is that which is paid on behalf of the Investigator and not reimbursed to the Investigator so that the exact monetary value may not be readily available), and/or reimbursed travel, whether in connection with an outside position or for consulting, lecturing, or service on a scientific advisory board, data safety monitoring board, steering committee for a clinical trial, executive committee for a clinical trial, or other committee for an outside entity, or for any other purpose including the purpose of the trip, the identity of the sponsor/organizer, the destination and the duration

The term "Financial Interest" does not include:

- (i) Salary or other remuneration received from the institution/organization
  - (ii) Grant support for salaries from the institution/organization
  - (iii) Holdings in mutual funds or 401K/403B retirement funds
  - (iv) *De minimus* gifts whose aggregate value does not exceed \$100 per annum; or reasonable business expenses.
- **Financially Interested Company** – An entity whose financial interests could reasonably appear to be affected by the conduct or outcome of a research project. The term "entity" means any corporation, limited liability company, partnership, limited partnership, limited liability partnership, joint venture, business trust, or other business organization, and any not-for-profit organization, charity or foundation.
  - **Related Party** – Spouse, domestic partner, and dependent children, siblings, or parents residing with the individual, or equivalents by marriage, or other individuals residing in the household.
  - **Significant Financial Interest** – A Financial Interest that is over \$5,000, or is less than \$5,000, and also involves a non-financial role in a Financially Interested Company, or is less than \$5,000, and the value cannot be determined through reference to publicly available prices, if the value will be affected by the outcome of the research, or the value represents 5% or more interest in any one single entity, and is determined by the COIC to be related to the research.



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All members of the study team (i.e. **key study personnel**) must complete and submit this form.

<p><b><i>Study for which this disclosure is provided (forms not attributable to a study will not be accepted):</i></b></p> <ul style="list-style-type: none"> <li>• <u>STUDY TITLE:</u></li> <li>• <u>LOCAL PRINCIPAL INVESTIGATOR:</u></li> <li>• <u>SPONSOR NAME &amp; ID:</u> <span style="float: right;"><u>BRANY Study ID:</u></span></li> </ul>		
a)	Within the <i>last 12 months</i> , have you or, to the best of your knowledge, has any related party <b>performed any work</b> (not directly related to the costs of conducting research) <u>for a Financially Interested Company</u> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
b)	Within the <i>last 12 months</i> , have you or, to the best of your knowledge, has any related party <b>received compensation</b> (not directly related to the costs of conducting research) <u>from a Financially Interested Company</u> ? Please answer Yes for paid/reimbursed travel (see definitions above).	<input type="checkbox"/> Yes <input type="checkbox"/> No
c)	Do you or, to the best of your knowledge, does any related party maintain <b>any board or executive relationship related to the research, regardless of compensation</b> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
d)	Within the next 12 months, have you or, to the best of your knowledge, does any related party anticipate <b>performing any work and/or receiving any compensation (not directly related to the costs of conducting research)</b> <u>from a Financially Interested Company</u> ? Please answer Yes for paid/reimbursed travel (see definitions above).	<input type="checkbox"/> Yes <input type="checkbox"/> No
e)	Do you or, to the best of your knowledge, does any related party <b>own stock, stock options or other forms of ownership</b> in <u>a Financially Interested Company</u> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
f)	Do you or, to the best of your knowledge, do any of your related parties have any <b>intellectual property related to the proposed research</b> (e.g., named as an inventor in an issued patent or patent application, license fees, technology transfers, current or future royalties from patents and copyrights)?	<input type="checkbox"/> Yes <input type="checkbox"/> No
g)	Does your <b>department/institution/organization</b> have a <b>financial interest</b> in the agent under investigation or in a company that could benefit from the study findings, or receive <b>significant financial support</b> from such a company?	<input type="checkbox"/> Yes <input type="checkbox"/> No
h)	Do you want to voluntarily disclose anything else?	<input type="checkbox"/> Yes <input type="checkbox"/> No
<p><b>For any YES answer to the above, complete and attach FORM 02: <u>Conflict Report Form</u>.</b></p>		
<p><b><i>Any change to the above responses must be promptly reported to BRANY IRB.</i></b>  <b><i>Any new significant financial interests must be reported within 30 days of acquisition or discovery.</i></b></p>		
_____ <b>Printed Name</b>	_____ <b>Signature*</b>	_____ <b>Date (mm/dd/yyyy)</b>

\*Wet ink signature is preferred. BRANY IRB recognizes this may be challenging due to COVID-19 restrictions. BRANY IRB will temporarily accept digital/electronic signatures as follows:



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Acceptable digital/electronic signatures

- Digital signatures created using Adobe Acrobat's digital signature function, or other 21 CFR 11 compliant digital signature applications.
- A graphic image of a **signature** placed on a document using secure software that verifies the identity of the user on the other end (e.g. DocuSign) is valid.

Generally, the digital/electronic signatures that are acceptable are ones that cannot be edited by others who receive it. These are signatures that can be verified to be the authorization/signature of the individual.

UNACCEPTABLE DIGITAL/ELECTRONIC SIGNATURES

- A graphic image of a signature placed on a document that is not verified by secure software is not valid, *except if accompanied by an email from the signer's official organization email address verifying the individual's authorization to sign, and only as a last resort.*
- A typewritten name, regardless of font, that has not been verified by secure software is not valid, *except if accompanied by an email from the signer's official organization email address verifying the individual's authorization to sign, and only as a last resort.*