INSTRUCTIONS FOR COMPLETING THE RESEARCH HIPAA AUTHORIZATION FORM

Screen shots of the current Research HIPAA Authorization and corresponding instructions are provided below:

- **IRB#** - Enter the local UCLA IRB#.
  - If this is a reliance IRB, and the UCLA IRB is not reviewing and/or approving documents for the study, there should still be a local UCLA IRB# assigned to the study.
- **University of California** – Enter UCLA Health as the name of the Health System
- **Study Title** – Enter the Complete Title of the Study, as stated in the study protocol
  - Of note: the font will reduce in size if the title is too long. UCOP is aware of the issue, and will work to resolve. In the meantime, continue to enter the title of the study as is.
- **Principal Investigator’s Name**: Enter the name of the physician or researcher that is directing the study, along with his/her professional credentials (e.g. John Research, M.D.; Jane Doe, Ph.D.)
- **Sponsor/Funding Agency (if funded)**:
  - If the Sponsor is also funding the study:
    - Enter the name of the study sponsor (e.g. Abbott Pharmaceuticals; National Institutes of Health, etc.)
    - If UCLA is the sponsor and funder of the study, enter UCLA
  - If the Sponsor and Funding agency are different (i.e. if UCLA is the sponsor who holds IND or the IDE but the pharma entity is providing financial support):
    - Enter Sponsor’s name as UCLA
    - Enter Funding Agency’s name (e.g. Merck Pharmaceuticals, etc.)
In Section A above, enter **UCLA Health** in both boxes.

In Section B above, enter **UCLA Health, NOT** a doctor’s name (as UCLA Health is the entity that will be releasing the patient’s information for research purposes)

In section B, best practice is **not to pre-check** the boxes, but to allow the prospective study participant to check the boxes that are applicable to the documents that will be released and used for research.

- Only the minimum necessary documents should be released.
- The study team may instruct the participant which boxes will need to be checked.
- If “other” is checked, the participant must specify what is being released (e.g. MRI dated _____; thyroid blood test dated ______, etc.)
C. Do I have to give my permission for certain specific uses?
Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

- [I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.
- [I agree to the release of HIV/AIDS testing information.
- [I agree to the release of genetic testing information.
- [I agree to the release of information pertaining to mental health diagnosis or treatment.

- In section C above, the prospective study participant must provide initials in the spaces that apply to the sensitive information that will be released for research purposes.
  - Of note, if none of the information denoted in section B will be required for research, then the participant should not place initials in any of the boxes.
  - One or more boxes in section C should only be initialed if the Informed Consent Form states that this information will be used for research purposes.

D. Who will disclose and/or receive my Personal Health Information?
Your Personal Health Information may be shared with these people for the following purposes:
1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research;
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor ________ (Sponsor Name) or the sponsor’s representatives, and including but not limited to ________ (CRO Name), or government agencies in other countries.

- In section D above:
  - Enter the Sponsor’s name (e.g. Merck Pharmaceuticals, National Institutes of Health, UCLA, etc.)
  - If there is a Contract Research Organization (CRO) that is contracted by the study sponsor to perform the administrative portion of the study (e.g. monitoring activities, financial reconciliation, etc.), then enter the CRO’s name;
    - If there is no CRO, enter N/A in this box

G. Optional research activity
If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

- [I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

- In section G above, the prospective study participant should check the box only if the informed consent states that additional research activities may or will occur as a result of the main study (e.g. sub-study will use the biological samples obtained during the main study for additional genetic analysis).
In section J above, the prospective study participant must print his/her name, and sign and date the form.

- If the prospective study participant is a child aged 0-17, the parent or Legally Authorized Representative (LAR) must sign the form on behalf of the child, and insert the date on the form.
- If the study is still ongoing and the study participant reaches the age of majority (in California, age of majority is 18), the study participant will need to execute a new Research HIPAA Authorization, with signature and current date. The parent is not required to sign the new form.
- A Legally Authorized Representative can execute the Research HIPAA Authorization on behalf of a prospective study participant, if the study participant is unable to do so (due to health status or other valid reason).
A witness signature is not required, unless the prospective study participant is unable to independently read and review the form.

**General Comments on the form:**

1) Since this is a UC Office of the President mandated form, no material changes can be made to the form.
   - This is the link to the correct version of the form on the UCOP webpage: [https://www.ucop.edu/ethics-compliance-audit-services/compliance/hipaa/hipaa-authorization-forms.html](https://www.ucop.edu/ethics-compliance-audit-services/compliance/hipaa/hipaa-authorization-forms.html)

2) If the prospective study participant's native language is not English, and the form requires translation to a language that is not readily available on the UCOP webpage, please contact the UCLA Health Interpreter Services to obtain a translation or to request the services of a translator.
   - The services of a translator should be secured prior to the consent conference date.

   - Click here to access the Interpreter Request Form
   - Telephone: (310) 267-8001
   - Email: interpreters@mednet.ucla.edu

3) Ensure that the Research HIPAA Authorization is executed in accordance with the requirements in the IRB approval letter (i.e. a general waiver of Research HIPAA Authorization may be granted for identification of study subjects; however, a research HIPAA authorization will still be required to allow for participation in the research study).

4) The fill-in information in the Research HIPAA Authorization does not require translation. Names of organizations, companies or entities can be entered in English (i.e. the name UCLA Health does not need to be translated).

5) For questions regarding this form, please contact the Office of Compliance Services at: compoffice@mednet.ucla.edu and request that your inquiry be routed to the Research Compliance team.